

**“A PROSPECTIVE RANDOMIZED STUDY
COMPARING THE EFFICACY AND CLINICAL
PROFILE OF DEXMEDETOMIDINE AND FENTANYL
AS AN ADJUVANT TO EPIDURAL ROPIVACAINE
FOR POSTOPERATIVE PAIN RELIEF IN SPINE
SURGERIES”**

Dissertation submitted to

THE TAMIL NADU DR. M.G.R.MEDICAL UNIVERSITY

In partial fulfilment for the award of the degree of

**DOCTOR OF MEDICINE IN ANAESTHESIOLOGY
BRANCH X**



**INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE
MADRAS MEDICAL COLLEGE
CHENNAI- 600003**

APRIL 2016

CERTIFICATE

This is to certify that the dissertation entitled, “**A PROSPECTIVE RANDOMIZED STUDY COMPARING THE EFFICACY AND CLINICAL PROFILE OF DEXMEDETOMIDINE AND FENTANYL AS AN ADJUVANT TO EPIDURAL ROPIVACAINE FOR POSTOPERATIVE PAIN RELIEF IN SPINE SURGERIES**” submitted by **Dr.M.BHASKAR**, in partial fulfillment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamil Nadu Dr. M.G.R. Medical University, Chennai., is a bonafide record of the work done by him in the **INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE**, Madras Medical College and government hospital, during the academic year 2014-2016.

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This is to certify that the dissertation entitled, **“A PROSPECTIVE RANDOMIZED STUDY COMPARING THE EFFICACY AND CLINICAL PROFILE OF DEXMEDETOMIDINE AND FENTANYL AS AN ADJUVANT TO EPIDURAL ROPIVACAINE FOR POSTOPERATIVE PAIN RELIEF IN SPINE SURGERIES”** submitted by **Dr.M.BHASKAR**, in partial fulfillment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamil Nadu Dr. M.G.R. Medical University, Chennai., is a bonafide record of the work done by him in the INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE, Madras Medical College and government hospital, during the academic year 2014-2016.

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DECLARATION

I hereby, solemnly declare that this dissertation entitled “**A PROSPECTIVE RANDOMIZED STUDY COMPARING THE EFFICACY AND CLINICAL PROFILE OF DEXMEDETOMIDINE AND FENTANYL AS AN ADJUVANT TO EPIDURAL ROPIVACAINE FOR POSTOPERATIVE PAIN RELIEF IN SPINE SURGERIES**” is a bonafide record of the work done by me in the Institute of Anaesthesiology and Critical Care, Madras Medical College and Government General Hospital, Chennai, during the period 2014 – 2016 under the guidance of **Prof .DR.M.VELLINGIRI, M.D., D.A** Professor of Anaesthesiology , Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai – 3 and submitted to **The Tamil Nadu Dr. M.G.R. Medical University, Guindy, Chennai – 32**, in partial fulfilment for the requirements for the award of the degree of M.D. Anaesthesiology (Branch X), examinations to be held on April 2016.

I have not submitted this dissertation previously to any university for the award of degree or diploma.

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INTRODUCTION

Spine surgeries are commonly associated with moderate to severe postoperative pain which is directly related to the invasiveness of the procedure. A large incision and manipulation of multiple vertebrae in spine surgeries contribute postoperative pain which remains a great challenge for the anaesthesiologist to treat it. Multimodal analgesic techniques like parenteral analgesics or regional analgesia are commonly practiced⁽¹⁾.

Conventional methods like intravenous or intramuscular analgesics are followed using opioids and 10 non-steroidal anti-inflammatory drugs (NSAID's).The opioids, though potent analgesics, are associated with 10 postoperative respiratory depression, nausea and vomiting, whereas less potent NSAIDs have limited use due to their renal and gastrointestinal side effects. The use of intrathecal opioids before surgical closure also provide effective postoperative analgesia without any major side effects⁽²⁾.

The use of local anaesthetics with adjuvants like opioids and alpha agonists through an epidural catheter placed intraoperatively under direct vision at the end of the procedure, is an effective alternative method for controlling postoperative pain

Good perioperative analgesia is important to attenuate the surgical stress response. Epidural analgesia reduces the adverse physiological

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INTRODUCTION

After surgery, patients are usually associated with problems in terms of postoperative pain which is directly related to the administration of the procedure. A large amount of manipulation of multiple variables in some surgical conditions postoperative pain which remains a great challenge for the anesthesiologist to treat it. Multimodal analgesic techniques like multimodal analgesia or regional analgesia are increasingly practiced⁽¹⁾.

Compared with the use of opioids, multimodal analgesia are followed using opioids and nonopioid analgesics such as NSAIDs⁽²⁾. The opioids through spinal analgesia are associated with postoperative respiratory depression, nausea and vomiting, which has great clinical facts based on the use of these analgesics and postoperative side effects. The use of multimodal analgesia before surgery decreases the postoperative analgesic postoperative analgesia without any major side effect⁽³⁾.

The use of local anesthetics with opioids like opioids and opioids through the spinal catheter placed intraoperatively under direct vision at the end of the procedure is an effective strategy needed for controlling postoperative pain.

Good postoperative analgesia is important to promote the rapid return to normal. Multimodal analgesia reduces the adverse physiological responses to surgery. The hyperactive sympathetic nervous system response, cardiovascular stress response, stress hormones, high metabolic rate, pulmonary dysfunction and immune system dysfunction⁽⁴⁾.

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ABSTRACT

PROSPECTIVE RANDOMIZED STUDY COMPARING THE EFFICACY AND CLINICAL PROFILE OF DEXMEDITOMIDINE AND FENTANYL AS AN ADJUVANT TO EPIDURAL ROPIVACAINE FOR POST OPERATIVE PAIN RELIEF IN SPINE SURGERIES

BACKGROUND AND OBJECTIVES:

Spine surgeries are commonly associated with moderate to severe postoperative pain which remains a great challenge for the anaesthesiologist to treat it. Multimodal analgesic techniques like parenteral analgesics or regional analgesia are commonly practiced. Use of intrathecal opioids before surgical closure provide effective postoperative analgesia without any major side effects. This study was designed to compare the analgesic efficacy of Ropivacaine and Dexmedetomidine (RD) with Ropivacaine and Fentanyl (RF) by giving these drugs by epidural administration in patients undergoing elective spine surgeries.

MATERIALS AND METHODS:

Prospective, randomized, double blinded study was conducted at Institute of Anaesthesiology and Critical Care, Rajiv Gandhi Government General Hospital, Chennai for a period of one year after ethical committee approval. 60 patients were randomly selected based on inclusion criteria and after obtaining written informed consent, patients were allocated into two equal groups. (RD & RF) and the data were analysed.

RESULTS:

The onset of sensory analgesia was earlier in Ropivacaine Dexmedetomidine (RD) group (5.93 ± 0.700 min) than Ropivacaine Fentanyl (RF) group (7.67 ± 0.702 min), peak effect of analgesia was 12.07 min for RD group and 13.13 min for RF group, mean duration of analgesia was significantly longer in RD group than RF group (349.80 ± 8.124 min vs 298.20 ± 4.77 min). Both groups showed haemodynamic stability. Visual Analogue Scale score between group

RD and RF was 1.79 and 2.31. Rescue analgesic requirement was less with RD group. Mean sedation score at various time intervals was significant between these groups. No episode of respiratory depression was noted in RD group.

CONCLUSION:

Concluded from this study that epidural route provided adequate analgesia in both groups. However, Dexmedetomidine seems to be a better alternative to Fentanyl as it provides early onset and establishment of sensory anesthesia, prolonged postoperative analgesia, lower consumption of postoperative rescue analgesia, comparable stable hemodynamics, and much better sedation levels.

KEYWORDS: Epidural analgesia, Ropivacaine, Dexmedetomidine, Fentanyl.

INTRODUCTION

Spine surgeries are commonly associated with moderate to severe postoperative pain which is directly related to the invasiveness of the procedure. A large incision and manipulation of multiple vertebrae in spine surgeries contribute postoperative pain which remains a great challenge for the anaesthesiologist to treat it. Multimodal analgesic techniques like parenteral analgesics or regional analgesia are commonly practiced¹.

Conventional methods like intravenous or intramuscular analgesics are followed using opioids and non-steroidal anti-inflammatory drugs (NSAID's). The opioids, though potent analgesics, are associated with postoperative respiratory depression, nausea and vomiting, whereas less potent NSAIDs have limited use due to their renal and gastrointestinal side effects. The use of intrathecal opioids before surgical closure also provide effective postoperative analgesia without any major side effects².

The use of local anaesthetics with adjuvants like opioids and alpha agonists through an epidural catheter placed intraoperatively under direct vision at the end of the procedure, is an effective alternative method for controlling postoperative pain

Good perioperative analgesia is important to attenuate the surgical stress response. Epidural analgesia reduces the adverse physiological responses to surgery like hyperactive autonomic nervous system response, cardiovascular stress response, tissue breakdown, high metabolic rate, pulmonary dysfunction and immune system dysfunction³.

By placing a catheter in the epidural space, continuous anaesthesia can be maintained for a long period of time . Epidural catheter can also be used to provide postoperative analgesia with lower concentrations of local anesthetic drugs alone or with adjuncts. Early postoperative mobilization and rehabilitation with minimal associated pain and discomfort is the most desirable feature in modern orthopedic surgeries³. This can be done by using a local anesthetic with lesser propensity of motor block.

Ropivacaine, the newer amide local anesthetic with minimal cardiovascular, central nervous system toxicity as well as lesser propensity of motor block has been used in this study. Traditionally opioids have been used as adjuvant to achieve the desired anesthetic effect with a lower dose of local anesthetic and superior analgesia.

Dexmedetomidine, is a new addition to the class of alpha-2 agonists, and a close congener of Clonidine, has been used for this purpose with many beneficial effects. Dexmedetomidine, is an imidazoline derivative, which is 1600 times more selective for alpha-2 receptors than alpha-1 receptors. It acts on both pre- synaptic and post- synaptic sympathetic nerve terminals and on the central nervous system thereby decreasing the sympathetic outflow and Norepinephrine release causing sedative, anti-anxiety, analgesic, sympatholytic effects. The anti nociceptive action is due to its effect at the spinal cord alpha -2 receptors⁴.

This study was designed to compare the analgesic efficacy of Ropivacaine with Dexmedetomidine and Ropivacaine with Fentanyl by their epidural administration in patients undergoing elective spine surgeries.

DEFINITION OF PAIN

Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”⁵.

CLASSIFICATION OF PAIN:

- 1) acute pain.
- 2) chronic pain.

Acute pain has feature of sudden onset and recedes during healing process. This pain is considered as good pain because it serves as an important protective mechanism, an example of this is the withdrawal reflex.

Chronic pain which means inflammatory and neuropathic pain, is considered as bad pain since it persists for a longtime after recovery from injury. This is refractory to common analgesics such as NSAIDs and opioids. Chronic pain results from nerve injury which includes diabetic neuropathy, toxin induced nerve injury and ischemia.

POST OPERATIVE PAIN⁶

During surgical tissue injury there is a release of inflammatory mediators like bradykinin, prostaglandins, serotonin and histamine. This activates the peripheral nociceptors and transmits the impulses through A delta and C fibers to the dorsal horn of spinal cord . This pain when uncontrolled, postoperatively ,has detrimental effects which are both acute and chronic. The predominant neuro endocrine response to pain includes the hypothalamo - pituitary -adrenocortical and the sympathoadrenal interactions which result in increased release of catecholamines and catabolic hormones like cortisol, increased sympathetic tone and decreased anabolic hormones. The extent of stress depends upon the type of anaesthesia and intensity of the surgical injury.

EFFECTS OF POST OPERATIVE PAIN:

(i) Cardiovascular system: The uncontrolled post operative pain causes hypertension, tachycardia, myocardial irritability and increased systemic vascular resistance. Cardiac output increases in most of the normal patients. The myocardial oxygen demand increases which may precipitate myocardial ischemia.

(ii) Respiratory system: The minute ventilation increases due to increase in oxygen consumption and with the carbon dioxide production which ultimately results in increase in the work of breathing more important in patients with underlying lung disease. Abdominal and thoracic incisions compromise the pulmonary function because of splinting and decrease the tidal volume and functional residual capacity, this leads to atelectasis, intra

pulmonary shunting and hypoxemia. The decreased vital capacity impairs the ability to cough and clear secretions.

(iii) Gastro intestinal system: The increased sympathetic tone, increases sphincter tone, decreases intestinal and bladder motility and causing ileus and urinary retention. Stress ulcers which occur due to hyperacidity may worsen the effects of pulmonary aspiration.

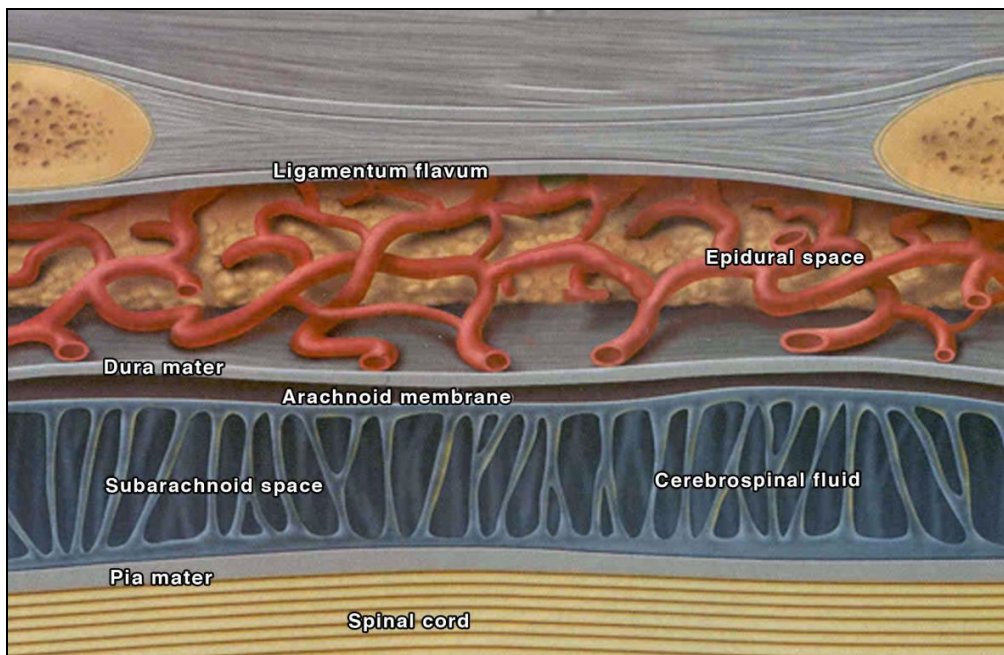
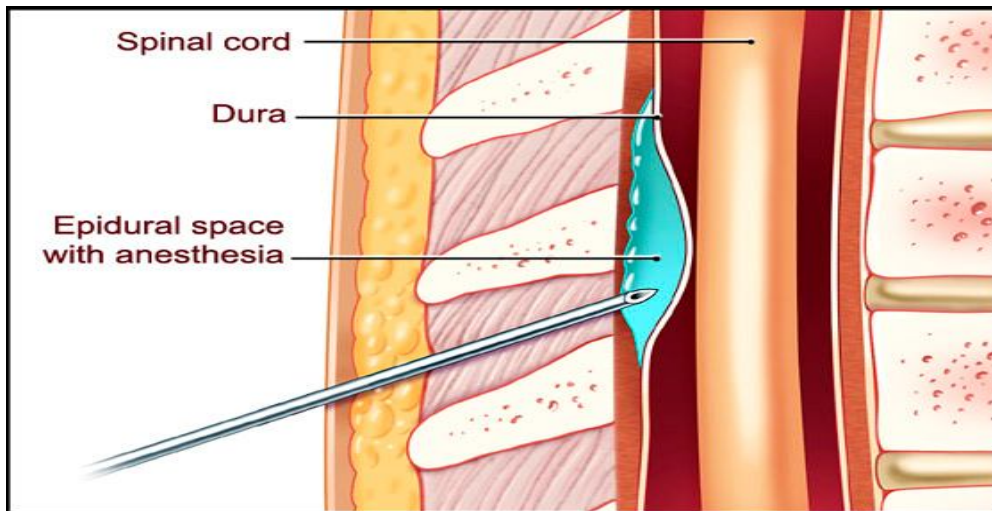
(iv)Endocrine effects: Stress increases the catabolic hormones like catecholamines, cortisol and glucagon and decreases the anabolic hormones like insulin and testosterone. This results in negative nitrogen balance, hyperglycaemia, increased lipolysis, sodium and water retention.

(v) Haematological effects: This includes increased platelet adhesiveness, decreased fibrinolysis and hypercoagulability of blood.

(vi) Musculo skeletal system effects: Restricted mobility due to pain leads to pressure sores and an increased risk for deep vein thrombosis.

(vii) Psychological effects: Sleep disturbance, anxiety, fatiguability and depression.

ANATOMY OF EPIDURAL SPACE⁷



VERTEBRAL COLUMN

The vertebral column consists of 33 vertebrae (7 cervical, 12 thoracic, 5 lumbar, 5 fused sacral and 4 coccygeal) and four curves. The cervical and lumbar vertebrae have curves which are convex anteriorly and the thoracic and sacral vertebrae are convex posteriorly. These curves have a significant influence on the spread of local anaesthetics in the epidural and subarachnoid

space. The vertebral column is bound together by several ligaments which give stability and elasticity to it.

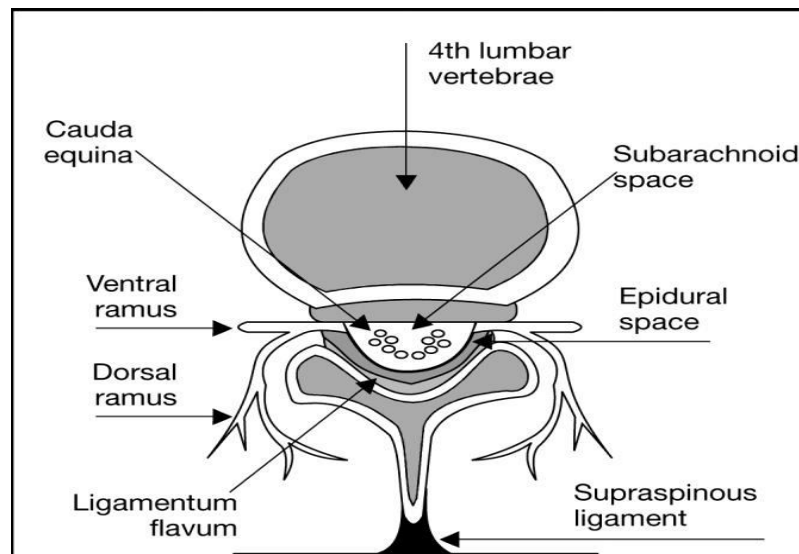
LIGAMENTS

- 1) Supraspinous ligament .It is a strong fibrous cord which connects the apices of spinous processes from sacrum to C7.It then extends to external occipital protuberance ,where it is called as the ligamentum nuchae.
- 2) Interspinous ligament – Thin membranous ligament which connects the spinous processes and blends anteriorly with ligamentum flavum and posteriorly with supraspinous ligament.
- 3) Ligamentum flavum – called as ‘ the yellow ligament’, comprises of yellow elastic fibres that connects adjacent lamina , it runs from the caudal edge of the vertebra above to the cephalad edge of the lamina below.
- 4) Longitudinal ligaments – the anterior and posterior longitudinal ligaments bind the vertebral bodies together.

The spinal cord is continuous above with the medulla oblongata, it begins at the level of the foramen magnum and ends below as the conus medullaris ,a thin thread filum terminale is attached to the coccyx. It ends the lower border of L₃ in newborn and lower border of L₁ in adult .It is cylindrical in shape, flattened in the lumbar region with the length of 45 cms.

There are totally 31 pairs of symmetrically arranged spinal nerve roots, eight Cervical , twelve Thoracic , five Lumbar , Sacral and one Coccygeal root . The cauda equina is formed by elongation of the nerve roots of lumbar and sacral region before they exit from the inter vertebral foramen.

SPINAL CORD STRUCTURES⁸



1) Epidural (extradural) space – It lies between the dura mater and periosteum. It extends from the foramen magnum to the sacral hiatus. It is a triangular space in cross-section, with two larger posterolateral and a small anterior compartments. It also extends through the spinal foramina (as the nerve roots exit) laterally. The depth of the epidural space is 3–5 cm from the skin, it is bounded by ligamentum flavum posteriorly, posterior longitudinal ligaments anteriorly and laterally by pedicles and intervertebral foramina.

The extradural space consists of adipose tissue, lymph vessels, arteries and venous plexus. The epidural space is widest in the midline and tapers off laterally. It is 5-6 mm in the mid lumbar region, whereas, in the thoracic region it is 3-5mm. Ligamentum flavum is the key landmark in epidural catheterization. It is composed mainly of elastic fibers, providing a unique clue for epidural needle placement using loss of resistance (LOR) technique.

2) Subdural space – It is the potential space between the arachnoid mater and duramater which contains thin serous fluid.

3) Subarachnoid space - It is the space between the arachnoid mater and pia mater which contains cerebrospinal fluid (CSF), spinal nerves, trabecular network between the two membranes, blood vessels that supply the spinal cord, lateral extensions of the pia mater and dentate ligaments. Although the spinal cord ends at the lower border of L1 in adults, the subarachnoid space continues up to the S2 segment.

4) Dura mater –It contains two layers of dense fibro elastic membrane in which the outer layer attaches to the foramen magnum and the inner layer continues as cerebral dura. The dura ends at the second sacral segment. It attaches to the coccygeal periosteum and covers the filum terminale. Anteriorly the dura is attached to the posterior longitudinal ligament and extends around the nerve roots laterally but it is free posteriorly.

5) Arachnoid mater – It is a delicate, nonvascular thin membrane closely lining the duramater. The arachnoid functions as the principal barrier to drugs crossing in and out of the CSF and is estimated to account for 90% of resistance to the drug migration.

6) Pia mater –A Highly vascular connective sheath that closely covers the spinal cord. The anterior part is thickened (linea splendens) and attached to the dura laterally (ligamentum denticulatum). Posteriorly, attaches to the dura by an incomplete sheet of pia (posterior subarachnoid septum). Inferiorly it is attached to the coccyx through filum terminale which is its continuation.

MECHANISM OF ACTION OF LOCAL ANESTHETICS⁹

Local anaesthetics act by preventing the activation of the sodium channel by binding to them in the inactivated state. The Development of action potential is prevented by blocking the movement of sodium ions into the cell membrane. This membrane stabilization property is the unique quality of local anaesthetics where repeated nerve stimulation will not affect the resting membrane potential.

MECHANISM OF ACTION OF LOCAL ANAESTHETICS IN NEURAL BLOCKADE

In the dorsal horn neurons, local anaesthetics act by blocking both sodium and potassium ion channels and thus inhibiting the generation of nociceptive electrical activity and thereby propagation of pain (noxious) signals. Similarly it acts on the ventral horn neurons to produce the motor blockade. Centrally administered local anaesthetics produce an intense analgesic action by blocking the Ca⁺ channels in the spinal cord. This may lead to resistance to electrical stimulation from afferent nerves carrying pain signals. Apart from these actions, local anaesthetics given through intrathecal route indirectly inhibit release of neurotransmitters like substance P, involved in pain signal processing. This leads to blockade of neurotransmitters like glutamate, calcitonin gene-related peptide (CGRP), neurokinin-1 and -2 (NK1, NK2) at the presynaptic level. Therefore local anaesthetics given intrathecally can indirectly inhibit the transmission of pain signals.

ORDER OF BLOCKADE IN REGIONAL ANESTHESIA⁹

The block and recovery of sensory fibers occur in this order

B-fibers -Preganglionic sympathetic fibers are most sensitive to local anaesthetic

C fibers – cold sensation

A δ – pin prick

A β – touch

A α - Vibration, proprioception and innervation to skeletal muscles

A α are less sensitive to local anaesthetics

SITE OF ACTION

The precise mode of action of an epidural drug has not been identified.

The proposed sites of action are²⁴:

- ❖ Spinal roots within the dural root sleeves as they traverse epidural space.
- ❖ Dorsal root ganglia
- ❖ Substance of spinal cord

INDICATIONS FOR EPIDURAL ANAESTHESIA

Epidural anaesthesia can be used for a variety of surgeries and conditions extending from the neck to the foot.

- 1) Prolonged orthopaedic surgeries like major hip/knee surgery, repair of pelvic fractures etc.

- 2) Obstetric, gynaecological surgeries and labour analgesia.
- 3) Urological surgeries involving prostate, bladder and ureters.
- 4) Epidural analgesia for upper abdominal procedures, thoracic procedures.
- 5) Paediatric caudal for lower abdominal surgeries and lower limb surgeries.

CONTRAINDICATIONS

(A) Absolute contraindication

- ❖ Patient refusal.
- ❖ Coagulopathy /Platelet count $<80,000 \text{ cells/mm}^3$
- ❖ Sepsis, infection at the puncture site
- ❖ Increased intracranial pressure.
- ❖ Severe hypovolemia,
- ❖ Severe aortic& mitral stenosis

(B) Relative contraindication

- ❖ Uncooperative patient
- ❖ Severe spine deformities
- ❖ Demyelinating lesions
- ❖ Hypertrophic obstructive cardiomyopathy

COMPLICATIONS OF EPIDURAL ANAESTHESIA

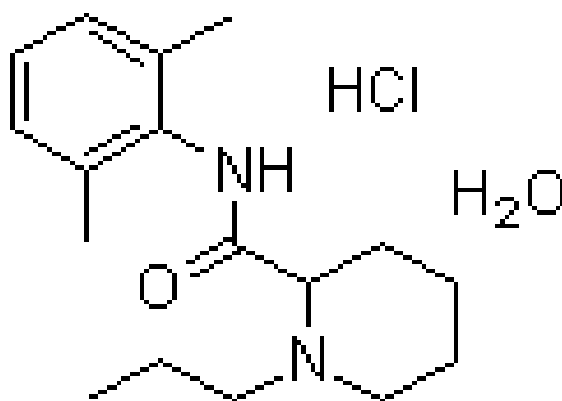
Major complications associated with epidural anaesthesia are

- 1) Direct trauma to the nerves
- 2) Systemic toxicity associated with inadvertent intravascular injection
- 3) Subdural injection of drugs,
- 4) Total spinal anaesthesia
- 5) Epidural abscess and meningitis.

Minor complications include backache, nausea, vomiting, postdural puncture headache, pneumocephalus, shivering .and urinary retention.

PHARMACOLOGY OF ROPIVACAINE⁽¹⁰⁾

Structure of Ropivacaine - Ropivacaine Hydrochloride: (S)-N-(2,6-dimethylphenyl)-1-propylpiperidine-2-carboxamide hydrochloride.



Molecular Formula $C_{17}H_{26}N_2O_2 \cdot HCl \cdot H_2O$: **Molecular Weight** 328

Ropivacaine belongs to the amide group of local anaesthetic drugs with both anaesthetic and analgesic properties. At high doses it produces anaesthesia and at lower doses it produces analgesia (sensory block) due to its differential blocking effect on nerve fibers. It belongs to a different local anaesthetic group, called the *pipecoloxylidides*, which was synthesized in 1957.

Ropivacaine is a local anaesthetic with increased duration of action, which is similar in structure to Bupivacaine. In contrast to Bupivacaine, Ropivacaine is a pure S (-) enantiomer¹¹, has reduced toxicity and at the same time improved sensory and motor block. It acts on different ion channels like sodium, potassium and calcium with different affinity that leads to greater reduction in neuronal toxicity and cardiovascular side effects. Ropivacaine is derived as a pure form of S (-) enantiomer from propivacaine, the parent molecule with chiral property. It belongs to the *pipecoloxylidides* group of local anaesthetics with the piperidine nitrogen atom having a propyl group.¹¹

Ropivacaine causes reversible blockade of impulse propagation by inhibition of sodium ion influx in nerve fibres. It inhibits potassium channel in a dose-dependent manner, because of less lipid solubility than Bupivacaine, it minimally penetrates the large myelinated A α motor fibres, explains its more specific action on the pain-transmission through A δ and C nerves rather than A α fibres (motor function).

Ropivacaine has a lesser propensity for cardiac and CNS adverse effects because of its stereo selective property. Its efficacy is similar to that of Levo Bupivacaine and Bupivacaine in blocking peripheral nerve, but when given neuraxially (epidural or intrathecal) it is less potent than Bupivacaine. It is also associated with lower grade motor blockade when compared to Bupivacaine. Because of its lower grade of motor blockade, there is reduced potential for CNS and cardiac adverse effects hence, it is a new agent of choice for regional anaesthesia¹².

PHARMACOKINETICS¹⁰

The plasma concentration depends on the dose, route of administration and vascularity of the injection site. Ropivacaine follows linear pharmacokinetics C_{max} is proportional to the dose. When given through epidural route its absorption is biphasic (t_{1/2} is 4.2 hrs) and complete. Elimination of Ropivacaine mainly depends on absorption which is the rate limiting step. The drug has longer half life when given epidurally. When given in the intravenous route it has the terminal half life about 1.8hrs.

Ropivacaine is highly protein bound particularly to α 1-acid glycoprotein and only 6% is present as unbound fraction. It crosses the

placenta easily and degree of plasma protein binding in fetus is less when compared to mother.

METABOLISM¹⁰

It is metabolized mainly in liver by aromatic hydroxylation by the enzyme cytochrome P450-1A . By IV route, a large amount of the drug for about 86% is excreted in urine. Out of this only, 1% is excreted as unchanged fragment. The important metabolite 3-hydroxy-ropivacaine is excreted after conjugation. The PPX (2', 6'-pipecoloxylidide) has longer $t_{1/2}$ and lower clearance after infusion by epidural. After epidural infusion N-dealkylated metabolite of Ropivacaine and 3-OH-Ropivacaine are the major metabolites excreted in the urine.

Clearance – unbound Ropivacaine – 13.94L/h/Kg

Clearance – Total Ropivacaine – 0.555L/h/Kg

Volume of distribution – 65.57L/min

Terminal $t_{1/2}$ of Ropivacaine - 3.3hrs

Terminal $t_{1/2}$ of PPX – 17.8 hrs

CONTRAINDICATIONS

- ❖ Hypersensitivity reactions to any amide group of local anaesthetics.
- ❖ Intravenous regional anaesthesia.
- ❖ Hypovolemic patients.

PRECAUTIONS

- ❖ Accidental intravenous administration results in cardiac arrest and convulsions.
- ❖ Retro bulbar block because of less clinical evidence.
- ❖ Patient with poor general condition
- ❖ Liver disease.
- ❖ Kidney dysfunction.
- ❖ Acute porphyria

DRUG INTERACTIONS

- ❖ Duration and intensity of block will not be altered by adding adrenaline.
- ❖ Additive effects with other local anaesthetics and Anti-arrhythmic drugs.
- ❖ With Fluvoxamine, Verapamil will prolong the half life.
- ❖ With Ketaconazole reduces the plasma clearance by 15 %.

INDICATIONS

- ❖ Epidural block for surgical anaesthesia in abdominal surgeries, pelvic, lumbar, lower limb and Caesarean section.
- ❖ Paediatric caudal block
- ❖ Spinal anaesthesia.
- ❖ Nerve blocks.
- ❖ Field and infiltration blocks.

DOSAGE AND ADMINISTRATION¹⁰

- ❖ Caudal – 1mg/kg 0.2% produces a block level below T12.
- ❖ Epidural block with 6-15 ml of 0.2% Ropivacaine provide adequate analgesia.
- ❖ Spinal – 2-3ml of 0.75 % (7.5mg/ml) .

Surgical anaesthesia	Concentration mg/ml	Volume (ml)	Dose(mg)	Onset (minutes)	Duration (hours)
Lumbar epidural, pelvic, and lower limb surgeries	5.0	15-30	75-150	15-30	2-4
	7.5	15-25	113-188	10-20	3-5
Nerve blocks	5.0	35-50	175-250	15-30	5-8
	7.5	10-40	75-300	10-25	6-10
Field block	5.0	1-40	5-300	1-15	2-6
	7.7	1-30	7.5-225	1-15	2-6

PREGNANCY AND LACTATION:

There are not many well documented studies in pregnant and nursing mothers.

ADVERSE EFFECTS:

Hypersensitivity reactions, Hypotension, bradycardia, vomiting, urinary retention,

CNS toxicity, cardiac toxicity, spinal cord dysfunction such as anterior spinal artery syndrome, arachnoiditis, cauda equina syndrome - less common

EPIDURAL ADMINISTRATION¹³:

Ropivacaine is less potent than Bupivacaine when equal volumes of similar concentration administered . Hyperbaric solutions have faster onset and a more reliable block with good recovery, because of the variability in spread and duration of the block ,but hyperbaric Ropivacaine solutions are not available. When administered with opioids, Ropivacaine not only reduces the total dose of local anaesthetic but also causes significant prolongation in the duration of complete and effective analgesia without increase in the duration of motor block.³

The potency of Ropivacaine in relation to Bupivacaine is 2/3rd with regard to sensory block and 1/2 with regard to motor block.

PHARMACOLOGY OF DEXMEDETOMIDINE

HISTORY¹⁴

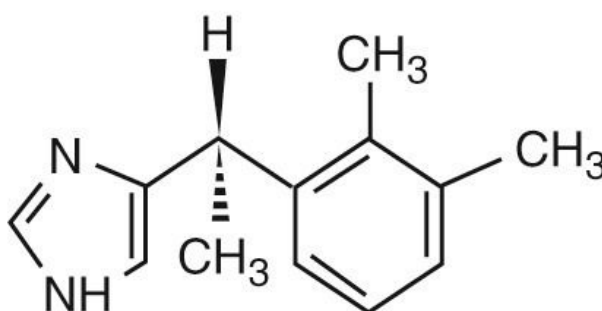
Historically α_2 -agonist were used in treating hypertensive patients and with withdrawal symptoms of alcohol and drug abusers. The α_2 -agonists provide sedation, anti-anxiety, hypnosis, analgesia and also inhibit sympathetic system.

Dexmedetomidine is more selective for α_2 receptors with 1600 times greater affinity for α_2 than α_1 receptor. It was introduced in 1999 as a short term sedative agent in ICU for adult patients on mechanical ventilation. But now it is widely used as a sedative, adjuvant analgesic for various diagnostic procedures.

PHYSIOCHEMICAL CHARACTERISTICS¹⁵

Dexmedetomidine is the d-enantiomer of medetomidine, belong to imidazole subgroup of α_2 agonist. The receptor specificity ratio 1600:1(α_2 : α_1), freely soluble in water.

STRUCTURE OF DEXMEDETOMIDINE



PHYSIOLOGICAL FUNCTIONS OF ALPHA 2 RECEPTORS

Alpha 2a – Presynaptic feedback inhibition of Norepinephrine release

Hypotension

Analgesia

Sedation

Inhibition of epileptic seizures

Alpha 2b – Hypertension

Placental angiogenesis

Analgesic effect of nitrous oxide

Alpha 2c –Feedback inhibition of adrenal catecholamine release

Analgesic effect of moxonidine

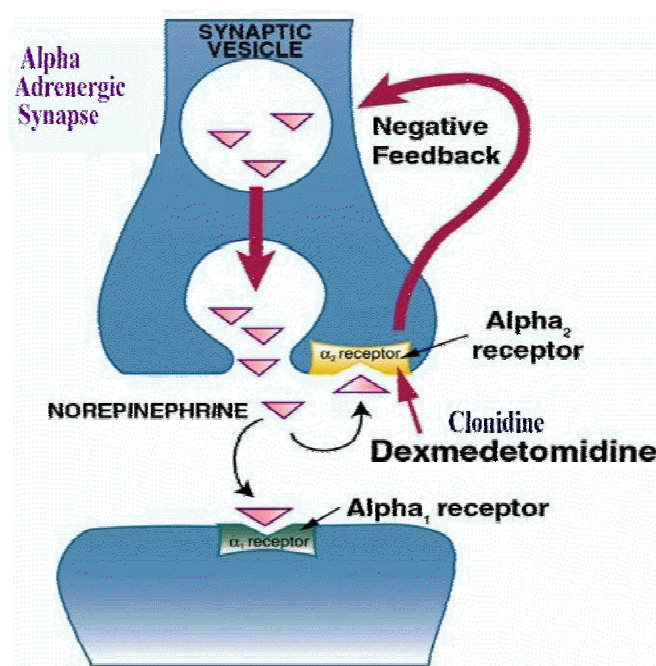
Modulation of behaviour

MECHANISM OF ACTION

- 1) Activates the inhibitory action of G proteins which leads to decrease in cyclic AMP.
- 2) Activate G proteins which directly act on membrane bound ion channels, more do on potassium channels.
- 3) Activates Nitric Oxide, Cyclic GMP pathway by inhibiting the release of Noradrenaline within neuronal tissue.

It causes hypotension and bradycardia in the dorsal motor complex of medulla. Its action on the locus coeruleus leads to analgesia and sedation. High density of receptors are present in the vagus nerve, intermediolateral column, substantia gelatinosa, dorsal horn of the spinal cord and also in primary sensory neurons.

ALPHA₂ ADRENOCEPTOR⁽¹⁴⁾



The α_2 receptors are G-protein coupled receptors present in the transmembrane region of central and peripheral nervous system, more particularly at the autonomic ganglion of pre synaptic and post-synaptic regions. Endogenous agonists such as nor epinephrine and exogenous agonists such as clonidine acts on these receptors and inhibit the enzymes, adenylycyclase and phospholipase C. This results in inhibition of calcium ion (Ca^{+}) entry and facilitates opening of potassium ion (K^{+}) channels outwards, and leads to hyperpolarization.

PHARMACOKINETICS

Dexmedetomidine undergoes rapid distribution and extensive metabolism in liver and is excreted in urine and feces. About 41% undergoes conjugation and 21% n-methylation 21%, or hydroxylation followed by conjugation. It has protein binding capacity of 94% to serum albumin and α_1 -glycoprotein, with half-life ($t_{1/2}$) of 6 minutes and elimination $t_{1/2}$ of about 2 hours; and volume of distribution around 118 litres. Clearance is about 39 L/h for a 72 kg person.

DISTRIBUTION

Dexmedetomidine has a plasma protein binding capacity of 94% which is constant for different concentration in plasma which is similar for both sexes. Patients with decompensated liver disease have decreased protein binding capacity.

METABOLISM

There is an almost complete biotransformation of Dexmedetomidine with very little unchanged amount which is excreted in urine and feces. Biotransformation occurs through both direct glucuronidation and cytochrome P450 mediated metabolism. The major metabolic pathways are:

- 1) Direct N-glucuronidation gives rise to inactive metabolites
- 2) Aliphatic hydroxylation (mediated primarily by CYP2A6) gives rise to 3-hydroxy-Dexmedetomidine, the glucuronide of 3-hydroxy-Dexmedetomidine, and 3-carboxyDexmedetomidine

- 3) N methylation of Dexmedetomidine gives rise to generate 3-hydroxy N-methyl-Dexmedetomidine, 3-carboxy N-methyl-Dexmedetomidine, and Dexmedetomidine-N-methyl O-glucuronide.

ELIMINATION

The Dexmedetomidine has a terminal elimination half-life ($t_{1/2}$) of approximately 2 hours and a clearance of approximately 39 L/h.

AGE AND GENDER

Dexmedetomidine hydrochloride does not show any variation in pharmacokinetics in both sexes and age groups.

PEDIATRICS

The researches are minimal in children regarding the pharmacokinetics.

HEPATIC IMPAIRMENT

Hepatic clearance values are lower, depend on the degree of hepatic derangement and the dosage is to be reduced depending on variations in liver function tests.

RENAL IMPAIRMENT

Dexmedetomidine hydrochloride pharmacokinetics do not vary in patients with severe renal impairment (creatinine clearance < 30 mL/min) when compared to healthy subjects. Since the metabolites are excreted in urine, they may accumulate on long term infusion.

DRUG INTERACTIONS

There is no evidence of cytochrome P450 mediated drug interactions that are likely to be of clinical relevance. When administered with anaesthetics, sedatives, hypnotics or opioids, it may lead to enhancement of their effects, so, they may need a reduction of dosage. It may have an additive effect with vasodilators and negative chronotropic agents. Midazolam and Propofol administration with Dexmedetomidine may lead to increased incidence of bradycardia and hypotension, hence more caution is required.

PREGNANCY, LABOUR AND LACTATION

There are no adequate and well controlled trials. Hence it should be used with caution.

ADVERSE EFFECTS

Most frequently observed side effects are hypotension, dry mouth, bradycardia and nausea. Other effects are fever, arrhythmias, AV block, extra systoles, pulmonary oedema, dizziness, headache etc.,

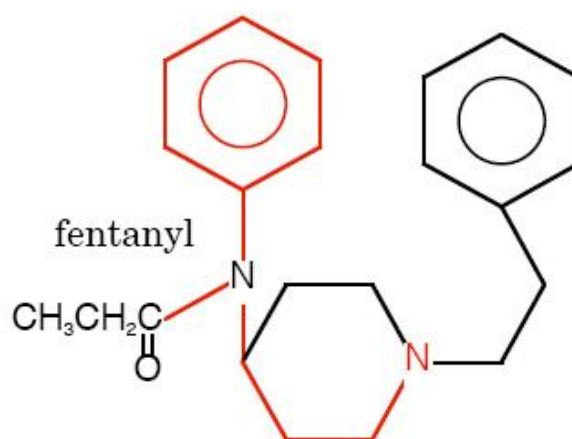
ALPHA 2 ANTAGONIST

Atipamezole¹⁶

Atipamezole, a selective alpha 2-adrenoceptor antagonist . Intravenous Atipamezole reverses the sedation and sympatholysis in dose a dependent manner . Due to the similar elimination half-lives for both agonist and the antagonist, the clinical effect of Dexmedetomidine after reversal by Atipamezole is very minimal. Therefore the Dexmedetomidine provides hypnosis and sedation in titrated doses and reversed readily by Atipamezole.

PHARMACOLOGY OF FENTANYL⁹

Fentanyl is a phenyl piperidine derivative of synthetic opioid agonist that is structurally related to Meperidine. Its analgesic efficacy is 100 times more potent than Morphine. It is available as a colorless solution in 2 and 10 ml ampoules with 50µg/ml. Its chemical structure is given as follows:



PHARMACOKINETICS

A single dose of Fentanyl has a more rapid onset and shorter duration of action than Morphine. The more rapid onset of action is due to its high lipid solubility, 500 times more lipid soluble than Morphine. The shorter duration of action is due to rapid redistribution to tissue sites such as fat, skeletal muscles. Plasma and CNS concentration falls below an effective level during rapid distribution phase at smaller doses (1-2µg/kg). The duration of action is prolonged while using higher doses or with frequent administration. In these circumstances, the plasma concentration is high even after the distribution phase is complete. Recovery from the drug effect depends upon the slow elimination of the drug (terminal half life-3.5hrs). The

lungs serve as inactive storage site with up to 75% of the drug undergoing first pass pulmonary uptake.

METABOLISM

It is metabolized in the liver by N-demethylation producing Norfentanyl, Hydroxy propionyl Fentanyl and Hydroxypropionyl Norfentanyl. Norfentanyl is the principal metabolite in humans and excreted by kidneys.

CLINICAL USES

It is administered in a wide range of clinical doses .Low dose 1-2µg/kg IV produces analgesia. In dose of 2-20µg /kg IV may be used as an adjuvant to inhalational anesthetics to blunt circulatory responses to direct laryngoscopy and sudden changes in the level of surgical stimulation. Administered in dose of 1.5 to 3 µg/kg IV, 5 minutes before induction decreases the requirement of inhalational anesthetics and subsequent opioid requirement in the postoperative period. Large doses up to 50 -150 µg/kg IV produces surgical anaesthesia. It can be used to augment effects of local anesthetics in spinal and epidural analgesia at dose of 10-25µg and 25-100µg respectively.

ADVANTAGES ¹⁷

Stable haemodynamics which are due to:

- 1) Lack of myocardial depressant effect
- 2) Absence of histamine release
- 3) Suppression of stress response to surgery

SIDE EFFECTS

- 1) Bradycardia
- 2) Myoclonus
- 3) Dose dependent respiratory depression .
- 4) Unconsciousness, muscular rigidity of the chest wall - at higher doses

DRUG INTERACTIONS

- 1) Potentiate the effects of Benzodiazepines
- 2) Decrease the dose requirements of Propofol.
- 3) Opioid Benzodiazepine synergism with respect to hypnosis and depression of ventilation

REVIEW OF LITERATURE

1. **Georgios Ekatodramis et al.(2002),¹⁸** studied in 23 patients in spine deformity surgeries. These introduced intraoperatively two epidural catheters through which bolus of Bupivacaine 0.0625% was injected followed by continuous infusion of Bupivacaine 0.0625%, Fentanyl 1-2 µg/ml and Clonidine 3 µg/ml and administered at a rate of 10 ml/hr through each catheter for 48 hr. They studied pain score, sedation level, motor block and side-effects. They concluded that postoperative epidural analgesia by means of a double catheter was an effective technique to control pain after spine deformity surgery and associated with a low incidence of side-effects

2..**RJ.Kumar, KV.Menan, TC.Ranjith et al.,(2003)¹⁹** did a retrospective study of the role of postoperative epidural analgesia in major spinal surgical procedures. They selected 74 patients who were undergoing spinal surgery and in those patients, after the end of surgery before the wound closure ,20 gauge epidural catheter was placed under direct vision 2.5 cm away from the main surgical incision. Post operatively those patients received various combination drugs such as Bupivaine with Fentanyl, Bupivacaine with Morphine and, Bupivaine with Buprenorphine.They concluded that Epidural analgesia was a safe and extremely useful modality in spinal surgery. All the drug combinations used in this study seemed to be equally effective in controlling postoperative pain.

3.**André Gottschalk et a.,l (2004)²⁰** conducted a prospective randomized, placebo-controlled, double-blind study in 30 patients undergoing

major spinal surgeries by giving an infusion of 12 ml/h Ropivacaine 0.1% (group R), and 12 ml/h saline (group N) after an initial bolus of 10 ml of the respective study solution. Both the groups were connected with intravenous PCA pump by the central venous line, using 1.5 mg of the Mu-receptor agonist Piritramide. The results obtained were as follows; continuous epidural infusion with 0.1% Ropivacaine resulted in significant reduction in VAS values during the whole study period. Satisfaction was higher in patients receiving epidural Ropivacaine. They concluded that significant pain relief and lower opioid requirement during a postoperative time of 72 hrs after lumbar spinal surgery when compared with intravenous PCA.

4. **Oriol-Lopez, Maldonado Sanchez et al.,** ²¹ (2008) conducted a prospective, descriptive study in 40 patients undergoing abdominal surgery under epidural anaesthesia. Dexmedetomidine at a dose of 1 µg/kg added to epidural Lignocaine produced Ramsay sedation score of 3 in 17% of the patients in 5 minutes, 90% of the patients had sedation score of 3-4 from 15-90 minutes, 4 % of patients had sedation score of 5 from 30-60 minutes. They concluded that adequate sedation (Ramsay sedation level of 3-4) was maintained between 10-120 minutes with a single bolus epidural dose of Dexmedetomidine

5. **Salgado PF et al (2008)et al**²² conducted a prospective randomized control study in 40 patients undergoing varicose vein and hernia surgeries under epidural anaesthesia. They compared 0.75% Ropivacaine (20 ml) with 0.75% Ropivacaine (20 ml) and Dexmedetomidine 1µg/kg. They observed the addition of Dexmedetomidine did not affect the onset time or upper level of

anaesthesia. However sensory and motor block duration was prolonged, post operative analgesia was longer and more intense motor block. BIS scores were lower in Dexmedetomidine group. There was no difference in incidence of hypotension and bradycardia. Occurrence of side effects namely vomiting, shivering and respiratory depression (spo2 <90%) was low and similar between the groups . They concluded that there exists a synergism between epidural Dexmedetomidine and Ropivacaine without additional side effects.

6. **Elhakim M, Abdelhamid D et al., (2010)**²³ conducted a comparative study in 50 adults who underwent thoracic surgery with epidural analgesia and one lung ventilation. They concluded that epidural dexmedetomidine 1µg/kg with bupivacaine 0.5% decreased the intra-operative anaesthetic requirements, prevented awareness during anaesthesia and improved post-operative oxygenation and post-operative analgesia.

7. **Mausumi Neogi et al.,**²⁴ (2010) did a comparative study on paediatric patients undergoing elective inguinal herniotomy. They compared the efficacy of Clonidine 1 µg/kg and Dexmedetomidine 1µg/kg as adjuvants to Ropivacaine for caudal analgesia.. They randomized the patients into 3 study groups, group R (Ropivacaine), group C (Ropivacaine + Clonidine), group D (Ropivacaine + Dexmedetomidine) and observed that, the mean duration of analgesia was 6.32±0.46 hours in group R, 13.17±0.68 hours in group C and 15.26±0.86 hours in group D. Duration of analgesia was significantly prolonged in both group C and group D in comparison to group R . They concluded that the addition of both Clonidine

and Dexmedetomidine with Ropivacaine administered caudally significantly increased the duration of analgesia.

8. **Gupta R Bogra et al., (2011)²⁵** did a study to compare Ropivacaine 0.75% with Ropivacaine and Dexmedetomidine 5µg by administering these drugs intrathecally in 60 patients. They concluded that the level of segmental regression to S2 and the duration of analgesia was significantly longer in Dexmedetomidine group also. Thus they also concluded that the addition of Dexmedetomidine prolonged the duration of analgesia.

9. **Sukhminder Jit Singh Bajwa et al., (2011)²⁶** conducted a randomized prospective study in 100 patients of ASA 1 and 2 between ages 21 and 56 years who underwent lower limb orthopedic surgery. They did comparison of epidural 0.75% Ropivacaine 15ml+Dexmedetomidine 1µg/kg (RD) with epidural 0.75% Ropivacaine 15ml+Fentanyl 1µg/kg(RF). They observed that Dexmedetomidine added to Ropivacaine produced earlier onset of sensory analgesia at T10 (7.12 ± 2.44 min) compared to Fentanyl (9.14 ± 2.94 min). The complete onset of motor blockade (18.16 ± 4.52 min) was earlier in Dexmedetomidine compared to Fentanyl (22.98 ± 4.78 min). Postoperative analgesia was also prolonged in Dexmedetomidine (366.62 ± 24.42) compared to Fentanyl (246.16 ± 23.86) and consequently lower consumption of local anaesthetic in Dexmedetomidine group. Dexmedetomidine group had better sedation scores. Side effects like nausea and vomiting were significantly higher in Fentanyl group (26% and 12%) while Dexmedetomidine group has higher incidence of dry mouth (14%)

.They concluded that Dexmedetomidine is a better alternative epidural adjuvant to Fentanyl.

10. **Vijay. G.Anand et al.**²⁷ (2011) conducted a study to compare the effects of caudal Dexmedetomidine combined with Ropivacaine to provide post operative analgesia in children. The study was conducted in 60 children who had undergone lower abdominal surgeries. They were allocated into 2 groups of 30 each. Group RD received 0.25% Ropivacaine 1 ml/kg with Dexmedetomidine 2µg/kg (made up to 0.5ml) and group R received 0.25% Ropivacaine 1ml/kg + 0.5 ml normal saline. Induction was done with 50% N₂O and 8% Sevoflurane in O₂ in spontaneous ventilation and then LMA was inserted. After that caudal block was performed and the study drug was given as mentioned above. The duration of post operative analgesia was recorded and median of 5.5 hrs in Group R compared with 14.5 hours in Group RD. Group R patients achieved and statistically significant higher FLACC score compared to RD patients. The mean sedation score, emergence behavior score, mean emergence time was statistically highly significant in RD Group. The peri-operative hemodynamics were stable in both groups. To conclude caudal Dexmedetomidine (2µg/kg) with 0.25% Ropivacaine 2ml/kg for paediatric lower abdominal surgeries achieved significant post operative pain relief that resulted in a better quality of sleep and prolonged duration of arousable sedation.

11. **Essam Shafiqet al.**, (2012)²⁸ conducted, a prospective randomized study in 72 children between the age group 8 months to 8yrs for infra-umbilical surgeries. The patients were allocated into 3 groups 24 each.

Group A(0.25% Ropivacaine 1ml/kg), Group B (0.25% Ropivacaine with Fentanyl 1 µg/kg), Group C (0.25% Ropivacaine and Dexmedetomidine 2 µg/kg). Patients were monitored for postoperative analgesia (FLACC score). Prolonged analgesia with less FLACC score(13.5hrs) in Group C ,compared to 4.5hrs and 8.5hrs in Group A and group B respectively.

12. Bhawna Rastogi et al ²⁹ (2013) done a study comparing the efficacy of epidural 0.75% Ropivacaine with Fentanyl(RF) with 0.5% Bupivacaine with Fentanyl (BF)for hemiarthroplasty in high risk patients. 60 patients of ASA 1&2 with no difference in their demographic profile were administered 15ml of either drug with 50µg of Fentanyl .Mean sensory level at T10 was achieved faster in RF group . The onset of complete motor block was also earlier in RF group than BF(17.5±3.4 vs. 21.7±7.8). Intra-operative hemodynamic parameters showed significant differences. They concluded that 0.75% Ropivacaine with Fentanyl as much better drug than Bupivacaine with fentanyl

13. Ajay Kumar Anandan et al.,(2014)³⁰ conducted a study comparing Ropivacaine with Dexmedetomidine (RD) with Ropivacaine (R) in 30 patients and concluded that the onset was earlier in RD (3.60min.) compared with R group (4.60 min.). and the duration of analgesia was prolonged in RD (289min.) compared to R group (243 min).

14. Manal M.Kamal et al., (2014)³¹ conducted a prospective study by allocating randomly sixty patients undergoing abdominal surgery into group I - Levobupivacaine Morphine (LM) group and group II: Levobupivacaine Dexmedetomidine (LD) group. Group I patients received 20 ml of 0.5%

Levobupivacaine (150 mg) and Morphine 1 mg. Group II patients received 20 ml of 0.5% Levobupivacaine and 1.5 µg/kg Dexmedetomidine. The onset, extent, duration of sensory and motor blocks, abdominal muscle relaxation and side effects were recorded. Time to reach motor block was shorter in the LM group than in LD group. There were no significant difference between the time of total regression of sensory or motor block and abdominal muscle relaxation. Regarding side effects, more patients in the LM group suffered from pruritis and more patients suffered from dry mouth in the LD group. They concluded that Dexmedetomidine is a good alternative to Morphine as an adjuvant to Levobupivacaine in epidural anaesthesia in major abdominal surgeries.

15 .**MS Saravana babu *et al.***, (2014)³² conducted a prospective randomized study in 60 patients to evaluate the efficacy and clinical profile of Dexmedetomidine and Clonidine as an adjuvant to Ropivacaine, for epidural analgesia in spine surgeries by giving 20 ml of 0.2% Ropivacaine and 1 µg/kg of Dexmedetomidine (group RD) or 20 ml of 0.2% Ropivacaine and 2 µg/kg of Clonidine (group RC).¹⁸

They observed that the addition of Dexmedetomidine to Ropivacaine as an adjuvant resulted in an earlier onset (7.33 ± 1.76 min) of analgesia as compared to the addition of Clonidine (8.40 ± 1.61 min). The duration of analgesia was also prolonged in Dexmedetomidine group (407.00 ± 47.06 min) compared to Clonidine group (345.01 ± 35.02). The need for IV rescue analgesics in both the groups was nil throughout the study period. The mean VAS score was higher in the Clonidine group at each time interval. They

concluded from the study that, the epidural route provided adequate analgesia in spine surgeries and RD Group had early onset, prolonged post operative analgesia and stable haemodynamics than RC Group.

16. **Sarabjit Kaur et al.**,³³ (2014) conducted a prospective, randomized double-blind study in 100 patients undergoing lower limb surgeries by randomly into groups receiving 150 mg of 0.75% Ropivacaine (Group A) and 150 mg of 0.75% Ropivacaine with Dexmedetomidine (1 µg/kg) (Group B). Two groups were compared with hemodynamic changes, block characteristics which included time to onset of analgesia at T10, maximum sensory analgesic level and time to the first dose of rescue analgesia. Significant difference was observed in relation to the duration of sensory block (375.20 ± 15.97 min. in Group A and 535.18 ± 19.85 min. in Group B, and consequently low doses of rescue analgesia in Group B (1.44 ± 0.501) as compared to Group A (2.56 ± 0.67). They concluded that Epidural Dexmedetomidine as an adjuvant to Ropivacaine associated with prolonged sensory and motor block, hemodynamic stability, prolonged postoperative analgesia and reduced demand for rescue analgesics when compared to plain Ropivacaine.

17) **Turner et al**³⁴, showed in an observational study that epidural catheters placed intraoperatively by the surgeon followed by infusion of local anesthetics with or without opioids were capable of providing good analgesia after posterior spinal fusion.

18) **Ravi prakash , B. B. Kushwaha, Shashibhushan, V.K.Bhatia, Girish Chandra and B.P.Singh et al**³⁵ did a comparative study of

Bupivacaine 0.25% alone and with Fentanyl or Dexmedetomidine for percutaneous nephrolithotomy (pcnl) under epidural anaesthesia. The study was conducted on 75 patients who were randomly allocated in three groups, Group A (n=25): patient receiving only 20 ml epidural 0.25% Bupivacaine. Group B (n=25): patient receiving 20 ml epidural 0.25% Bupivacaine along with Fentanyl (1mcg/kg) and Group C (n=25): patient receiving 20 ml epidural 0.25% Bupivacaine along with Dexmedetomidine (1mcg/kg). They observed that addition of Fentanyl and Dexmedetomidine prolongs the duration of analgesia. Dexmedetomidine was more effective in this respect. Time for 2 segment regression was 86.52 ± 9.07 minutes for Group A, 120.00 ± 5.95 minutes for . Group B and 135.40 ± 9.57 minutes for Group C.

AIM AND OBJECTIVES

Comparison of post operative analgesia using Epidural Ropivacaine and Dexmedetomidine with Ropivacaine and Fentanyl, in patients undergoing elective spine surgeries with respect to:

- 1) Onset of analgesia
- 2) Time of peak onset of analgesia
- 3) The duration of analgesia
- 4) The need of rescue analgesics
- 5) Post-operative haemodynamics

MATERIALS AND METHODS

The study was conducted at the Institute of Anaesthesiology and Critical Care, Rajiv Gandhi Government General Hospital, Chennai between 2014- 2015. Ethical committee approval was obtained from the institution. 60 patients were randomly selected based on inclusion criteria and after obtaining written informed consent , patients were allocated into two equal groups.

STUDY DESIGN

Prospective, randomized, double blinded study

STUDY PLACE

Institute of Anaesthesiology and Critical Care, Rajiv Gandhi Government General Hospital, Chennai.

STUDY PERIOD

2014- 2015.

STUDY POPULATION

60 Patients were selected and allocated in two groups

ETHICAL CONSIDERATION

Approval was obtained from the Institutional ethics committee before the commencement of the study. Informed consent was obtained from all the patients participated in this study. All patients satisfying the inclusion criteria were included. Patients were interviewed by structured questionnaire.

Statistical analysis: Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test and categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

INCLUSION CRITERIA

- ❖ Age : 20-65 years
- ❖ ASA : I & II
- ❖ Elective Surgeries
- ❖ Who have given valid informed consent.
- ❖ Lower thoracic below T8 and lumbosacral spine surgeries

EXCLUSION CRITERIA

- ❖ ASA III & IV
- ❖ Patients with heart block, Bradyarrhythmia and Left ventricular failure
- ❖ Hematological disease, Bleeding or coagulation abnormalities
- ❖ Psychiatric diseases, TB spine and any other permanent neurological disorders

PREOPERATIVE PREPARATION

Patients, age, body weight and baseline vital parameters were recorded. History regarding previous anaesthesia, surgery and other significant co morbid illness, medications and allergy was also recorded. Complete physical examination and airway assessment were done.

In the preoperative period all patients were explained about the benefits of Epidural anaesthesia and 10-point visual analogue scale and informed consent was obtained from the study group patients.

PREMEDICATION

All patients were premedicated with tablets Ondansetron 4mg and Ranitidine 150 mg at 6 am on the day of surgery. They also received tab. Diazepam 0.2mg/kg orally night before surgery.

MATERIALS USED

- ❖ 18 Gauge Tuohy needle, 20 Gauge Epidural catheter
- ❖ Drugs—inj. Ropivacaine, inj. Dexmedetomidine, inj. Fentanyl , emergency drugs and normal saline
- ❖ Monitors – Electro Cardio Gram, Noninvasive blood pressure monitor, pulseoximetry (spo2).



MONITORING AND INTRAVENOUS ACCESS

Continuous ECG and SpO₂, Noninvasive blood pressure monitoring done. Intravenous access was done using 16 or 18 Gauge venflon and crystalloid was started.

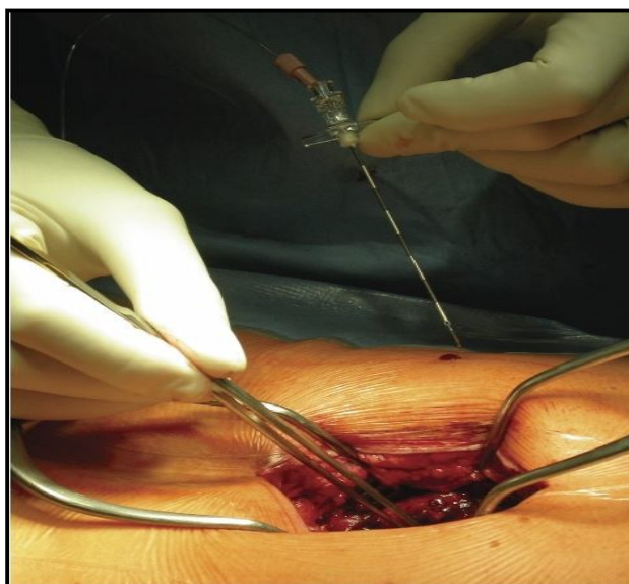
PROCEDURE

In the operation theatre the monitors were connected and baseline heart rate, SpO₂, blood pressure were recorded. All cases were premedicated with Inj.Glycopyrrolate 0.05mg/kg and with Inj.fentanyl 2µg/kg ,and induced with Thiopentone 5mg/kg. Intubation was done with Suxamethonium 1mg/kg and maintained by Atracurium 0.5mg/kg and Oxygen and Nitrous oxide in the ratio of 1:3.with volatile anaesthetics. After completion of the surgical procedure and before closure of the wound, 20 gauge epidural catheter was placed under direct vision in the epidural space by separate skin puncture about 2.5 cm away from the main surgical incision with 16 gauge Tuohy needle. The catheter was positioned up to 7 to 10 cm from skin entry directed upwards in the epidural space under direct vision. The catheter was secured in place on the back of the patient using an adhesive tape. After closing and dressing the surgical wound the patient was extubated after adequate reversal. Patients were shifted to post-anaesthetic care unit and monitored. Once the patient was noted to have pain (visual analogue scale (VAS) of >4), the study started. A test dose of 3 ml Lignocaine with Adrenaline (1:200,000) was injected and the patients were randomly allocated to one of the following two groups in a double-blinded method:

Group-1: (Ropivacaine + Dexmedetomidine (RD) (*n*=30); Ropivacaine 0.2% 15 ml plus Dexmedetomidine 1 mcg/kg.

Group-2: (Ropivacaine + Fentanyl (RF) (*n*=30); Ropivacaine 0.2% 15ml plus Fentanyl 1 mcg/kg.

Epidural catheter placement through seperate skin puncture from the main surgical incision with Tuohy needle.



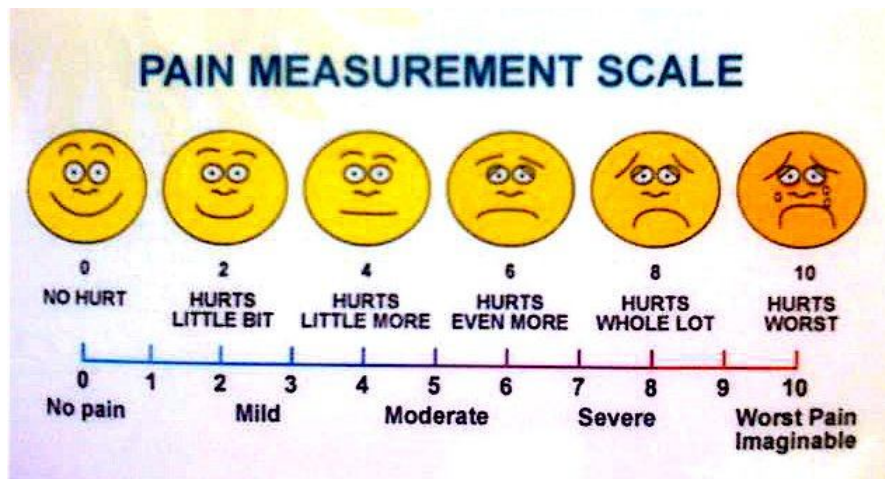
After administering the drug, the following parameters were recorded by the independent observer.

- 1) The pain score using Visual Analogue Scale (VAS) every 2 min for 30 min and then every 30 min until the need for next epidural top up.
- 2) Onset of analgesia (fall of VAS<4 after epidural drug).
- 3) Peak level of analgesia (achieving VAS score 0).
- 4) Duration of analgesia (starting from epidural drug administration to once the patient asks for additional rescue analgesia with VAS>4).
- 5) Monitoring of vital parameters such as NIBP, pulse rate, respiratory rate every 30 min.
- 6) Side-effects such as nausea, vomiting, respiratory depression, deep sedation (Ramsay sedation scale>3), shivering ,dry mouth , bradycardia and hypotension and requirement for IV rescue analgesics (injection Diclofenac).
- 7) Once the patient asked for additional epidural analgesia (VAS>4) for pain relief during the observation period, the study ended and the above mentioned parameters were noted.

RECORDING OF ADVERSE EFFECTS

Adverse events like hypotension, bradycardia, nausea, vomiting, dry mouth were noted. Hypotension (defined as systolic arterial pressure falling more than 20% from the pre-operative level) was treated with injection ephedrine 3-6 mg IV bolus and heart rate less than 50 beats/min was treated with 0.01 mg/kg of injection atropine. Post-operative maintenance IV fluids were given as per body weight. Nausea and vomiting were treated with 0.1 mg/kg of IV Ondansetron.

ASSESSMENT OF PAIN USING VISUAL ANALOG SCORE (VAS)



The pain was assessed using visual analogue scale rating from 0 to 10 during intra operative period

RAMSAY SEDATION SCORE

Table 1 – Ramsay scale ⁴	
1	Patient anxious and agitated or restless, or both
2	Patient co-operative, orientated, and tranquil
3	Patient responds to commands only
4	Brisk response to a light glabellar tap or auditory stimulus
5	Sluggish response to a light glabellar tap or auditory stimulus
6	No response to the stimuli mentioned in items 4 and 5

OBSERVATION AND RESULTS

Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test and categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

Table 1. Group distribution (n=60)

Groups	Group Names	Intervention Used	Procedure
RD	Ropivacaine + Dexmedetomidine.	Post- operative epidural block with Ropivacaine and Dexmedetomidine.	In post-operative patients who are undergoing elective spine surgeries
RF	Ropivacaine + Fentanyl.	Post- operative epidural block with Ropivacaine and Fentanyl.	

SAMPLE SIZE CALCULATION

Sample size was determined based on, the comparative study in the post-operative spine surgeries: Epidural Ropivacaine with Dexmedetomidine and Ropivacaine with Fentanyl for post-operative analgesia, Authored by MS Saravana Babu et al published in Indian Journal of Anaesthesia | Vol. 57 | Issue 4 | Jul-Aug 2013.

In this study the duration of analgesia has a mean difference of 62 minutes which is highly significant at 0.001.

DESCRIPTION

- ❖ The confidence level is estimated at 95%
- ❖ With a z value of 1.96
- ❖ The confidence interval or margin of error is estimated at +/-12
- ❖ Assuming that the sample will have the specified attribute p% =62 and q%=38

$$n = p\% \times q\% \times [z/e\%]^2$$

$$n=62 \times 38 \times [1.96/15]^2$$

$$n= 40.23$$

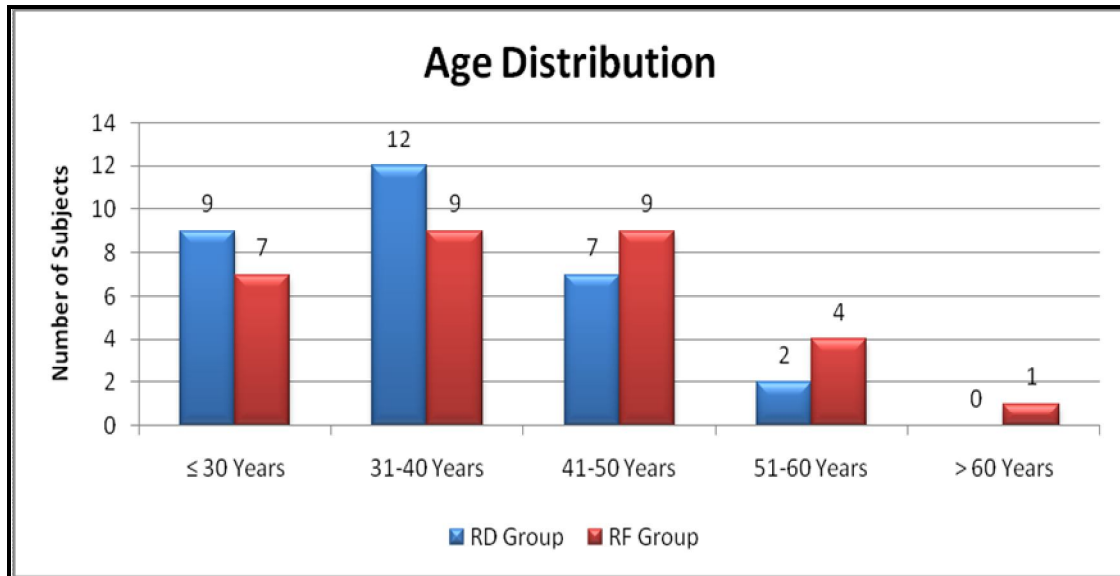
Therefore 40 is the minimum sample size required for the study

In our study we have taken 60 as the sample size.

Table-2: Age distribution (n=30 in Group RD and n=30 in Group RF)

Age Distribution	RD Group	%	RF Group	%
≤ 30 Years	9	30.00	7	23.33
31-40 Years	12	40.00	9	30.00
41-50 Years	7	23.33	9	30.00
51-60 Years	2	6.67	4	13.33
> 60 Years	0	0.00	1	3.33
Total	30	100	30	100

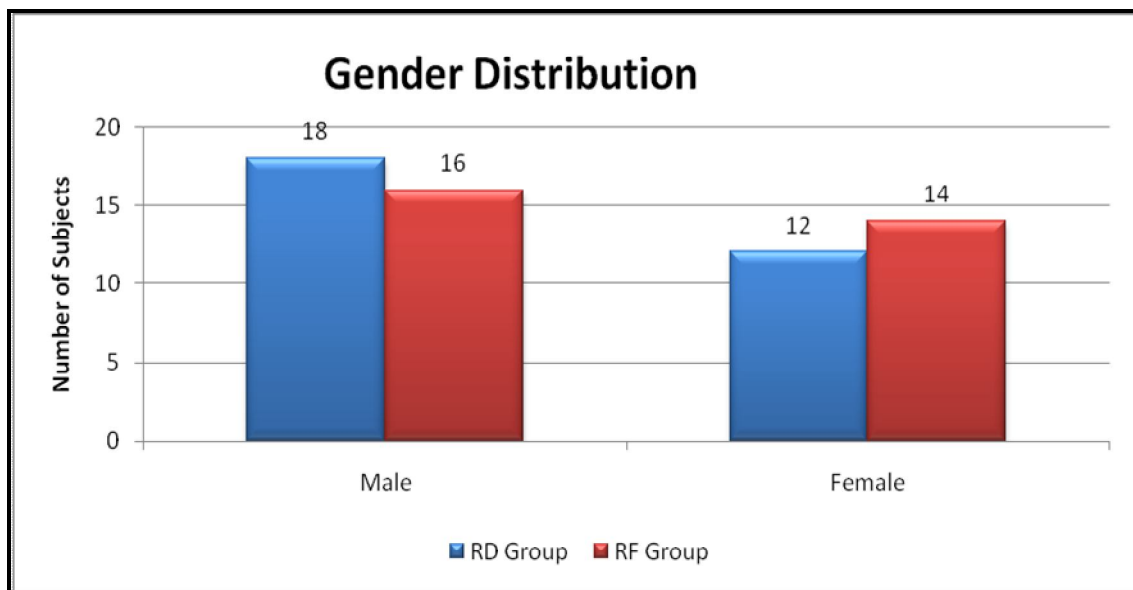
Age Distribution	RD Group	RF Group
N	30	30
Mean	36.10	39.50
SD	10.83	11.02
P value Unaired t test		0.233028



Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the 31-40 years age group (n=12, 40%) with a mean age of 36.10 years. In the Ropivacaine + Fentanyl group patients, majority belonged to the same age group as Ropivacaine + Dexmedetomidine group (n=9, 30%) with a mean age of 39.50 years. The association between the intervention groups and age distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 3. Gender distribution

Gender Distribution	RD Group	%	RF Group	%
Male	18	60.00	16	53.33
Female	12	40.00	14	46.67
Total	30	100	30	100
P value Fishers Exact Test			0.7948	

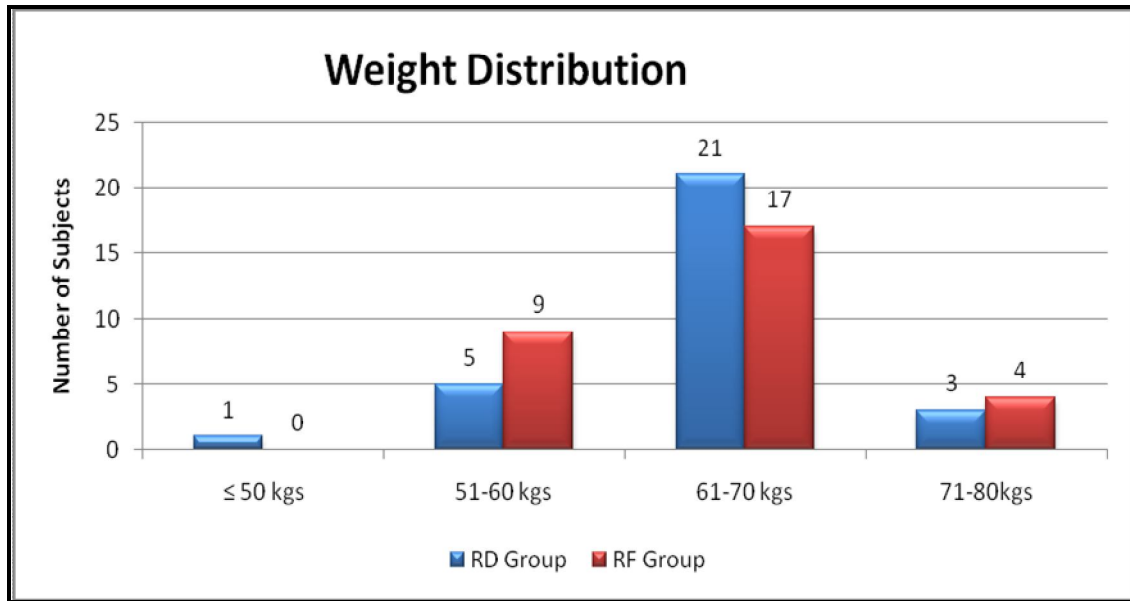


Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the male gender group (n=16, 60%). In the Ropivacaine + Fentanyl group patients, majority belonged to the male gender group (n=16, 53.33%). The association between the intervention groups and gender distribution is considered to be not statistically significant since $p > 0.05$ as per fishers exact test.

Table4.Weight distribution

Weight Distribution	RD Group	%	RF Group	%
≤ 50 kgs	1	3.33	0	0.00
51-60 kgs	5	16.67	9	30.00
61-70 kgs	21	70.00	17	56.67
71-80kgs	3	10.00	4	13.33
Total	30	100	30	100

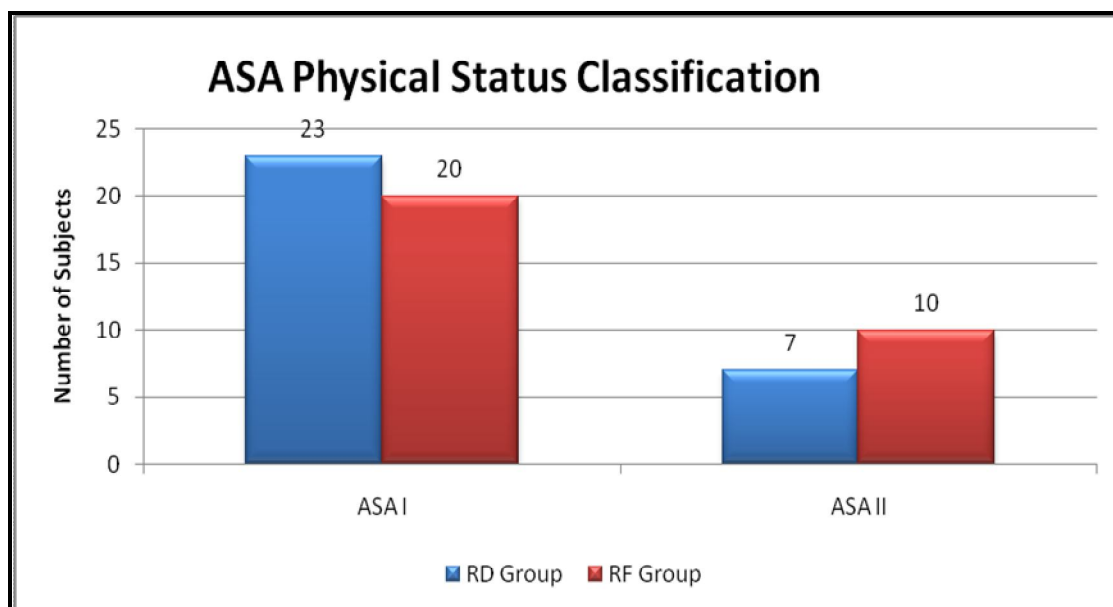
Weight Distribution	RD Group	RF Group
N	30	30
Mean	66.23	65.47
SD	5.77	6.41
P value Unaired t test		0.6282



Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the 61-70 kgs weight group (n=21, 70%) with a mean weight of 66.23 kgs. In the Ropivacaine + Fentanyl group patients, majority belonged to the same weight group as Ropivacaine + Dexmedetomidine group (n=17, 56.67%) with a mean weight of 65.47 years. The association between the intervention groups and weight distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 5. ASA physical status classification

ASA Physical Status Classification	RD Group	%	RF Group	%
ASA I	23	76.67	20	66.67
ASA II	7	23.33	10	33.33
Total	30	100	30	100
P value Fishers Exact Test			0.5675	

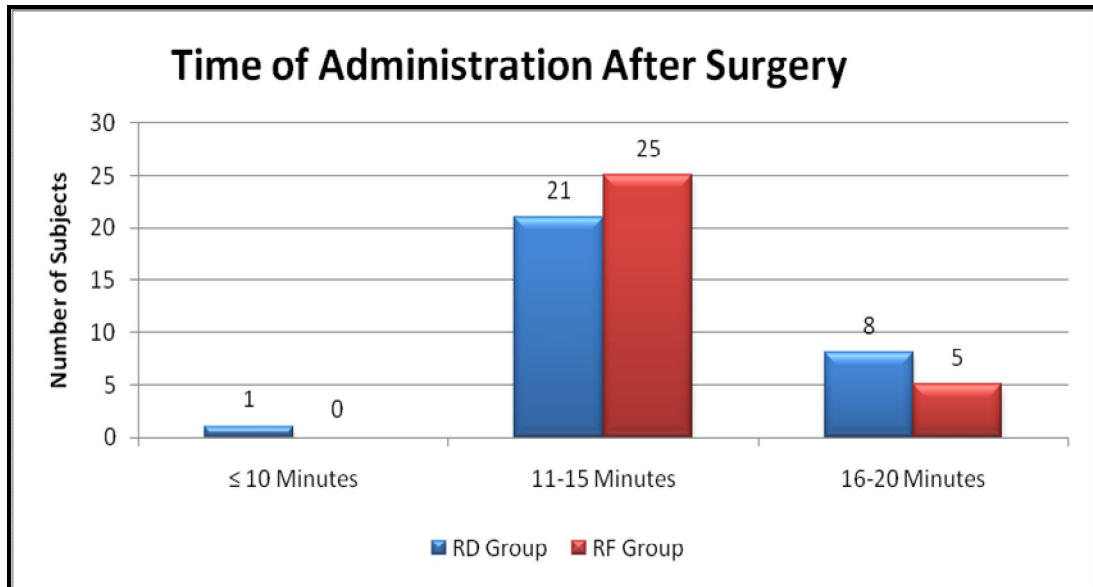


Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the ASA classification I group (n=23, 76.67%). In the Ropivacaine + Fentanyl group patients, majority belonged to the ASA classification I group (n=20, 66.67%). The association between the intervention groups and ASA physical status classification is considered to be not statistically significant since $p > 0.05$ as per fishers exact test.

Table6.Time of administration of drug after surgery

Time of Administration of drug After Surgery	RD Group	%	RF Group	%
≤ 10 Minutes	1	3.33	0	0.00
11-15 Minutes	21	70.00	25	83.33
16-20 Minutes	8	26.67	5	16.67
Total	30	100	30	100

Time of Administration After Surgery	RD Group	RF Group
N	30	30
Mean	16.07	14.97
SD	2.63	2.04
P value Unaired t test		0.0756

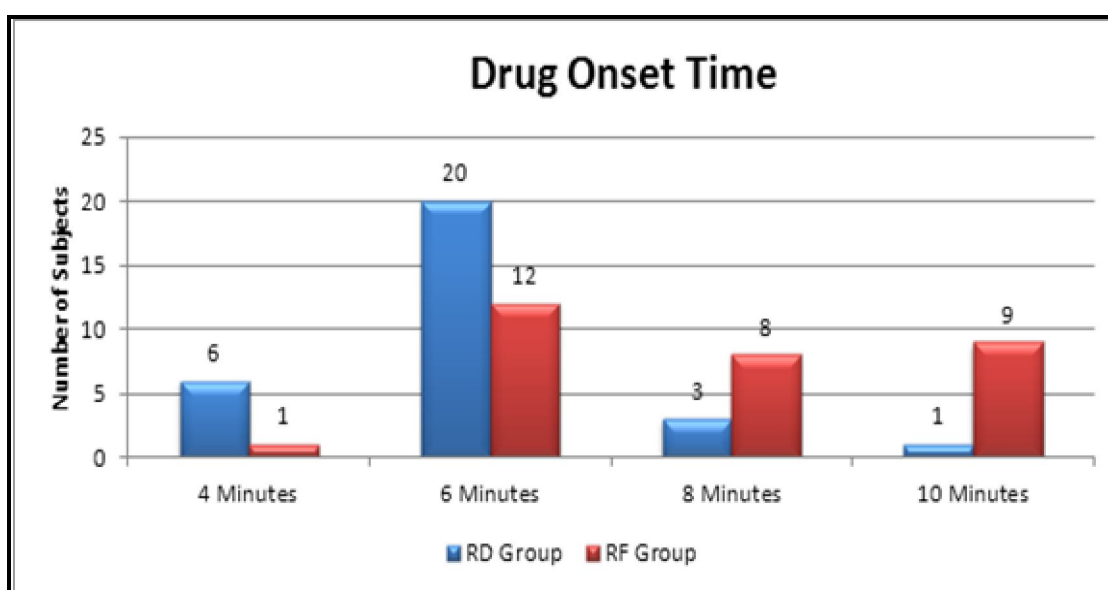


Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the 11-15 minutes after surgery drug administration time group (n=21, 70%) with a mean time of administration after surgery of 16.07 minutes. In the Ropivacaine + Fentanyl group patients, majority belonged to the same class interval as Ropivacaine + Dexmedetomidine group (n=25, 83.33%) with a mean time of administration after surgery of 14.97 minutes. The association between the intervention groups and time of administration after surgery distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 7. Drug Onset Time

Drug Onset Time	RD Group	%	RF Group	%
4 Minutes	6	20.00	1	3.33
6 Minutes	20	66.67	12	40.00
8 Minutes	3	10.00	8	26.67
10 Minutes	1	3.33	9	30.00
Total	30	100	30	100

Drug Onset Time	RD Group	RF Group
N	30	30
Mean	5.93	7.67
SD	1.34	1.83
P value Unaired t test		0.0001



By conventional criteria the association between the intervention groups and drug onset time is considered to be statistically significant since $p < 0.05$ as per unpaired t test. In simple terms, Most of the Ropivacaine + Dexmedetomidine group patients belong to 6 minutes drug onset time class interval ($n=20$, 66.67%) with a mean drug onset time of 5.93 minutes. Similarly in the Ropivacaine + Fentanyl group majority of the patients belonged to the 6 minutes drug onset time class interval ($n=12$, 40%) with a mean drug onset time of 7.67 minutes. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0001.

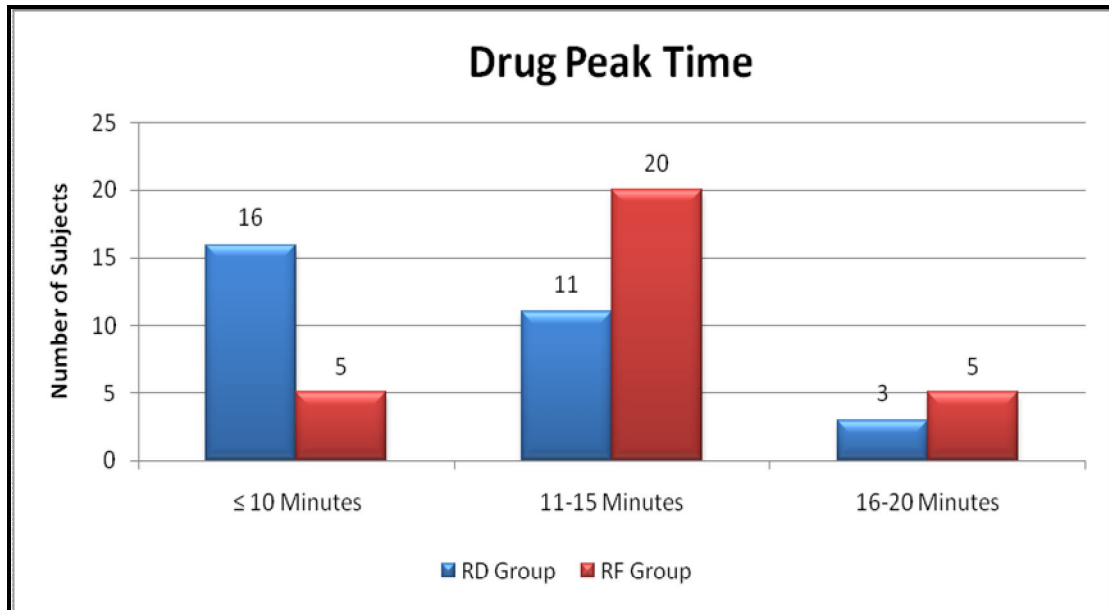
The mean drug onset time was meaningfully less in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean time of 1.73 minutes. This significant difference of 23% reduction in mean drug onset time among patients belonging to Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance.

In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmedetomidine results in significantly lowered drug onset time compared to Post- operative epidural block with Ropivacaine + Fentanyl when used in post-operative patients who underwent elective spine surgeries

Table 8. Drug Peak Time

Drug Peak Time	RD Group	%	RF Group	%
≤ 10 Minutes	16	53.33	5	16.67
11-15 Minutes	11	36.67	20	66.67
16-20 Minutes	3	10.00	5	16.67
Total	30	100	30	100

Drug Peak Time	RD Group	RF Group
N	30	30
Mean	12.07	13.13
SD	3.08	2.27
P value Unaired t test		0.1330

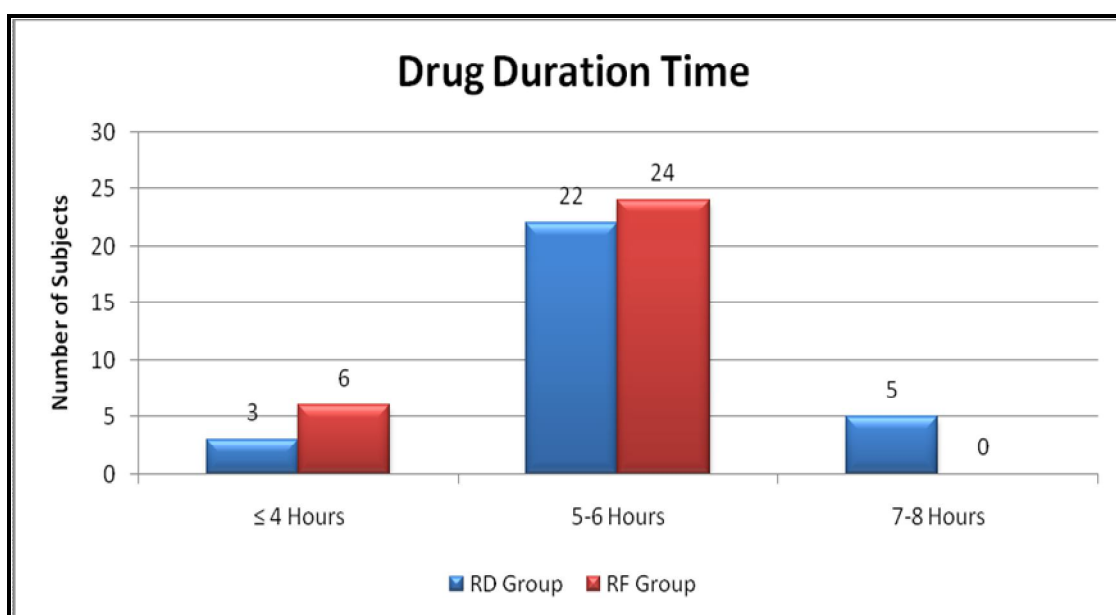


Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the ≤ 10 minutes drug peak time class interval (n=16, 53.33%) with a mean drug peak time of 12.07 seconds. In the Ropivacaine + Fentanyl group patients, majority belonged to 11-15 minutes drug peak time class interval (n=20, 66.67%) with a mean drug peak time of 13.13 seconds. The association between the intervention groups and drug peak time distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 9. Drug Duration Time

Drug Duration Time	RD Group	%	RF Group	%
≤ 4 Hours	3	10.00	6	20.00
5-6 Hours	22	73.33	24	80.00
7-8 Hours	5	16.67	0	0.00
Total	30	100	30	100

Drug Duration Time	RD Group	RF Group
N	30	30
Mean	5.83	4.97
SD	0.99	0.72
P value Unaired t test		0.0003



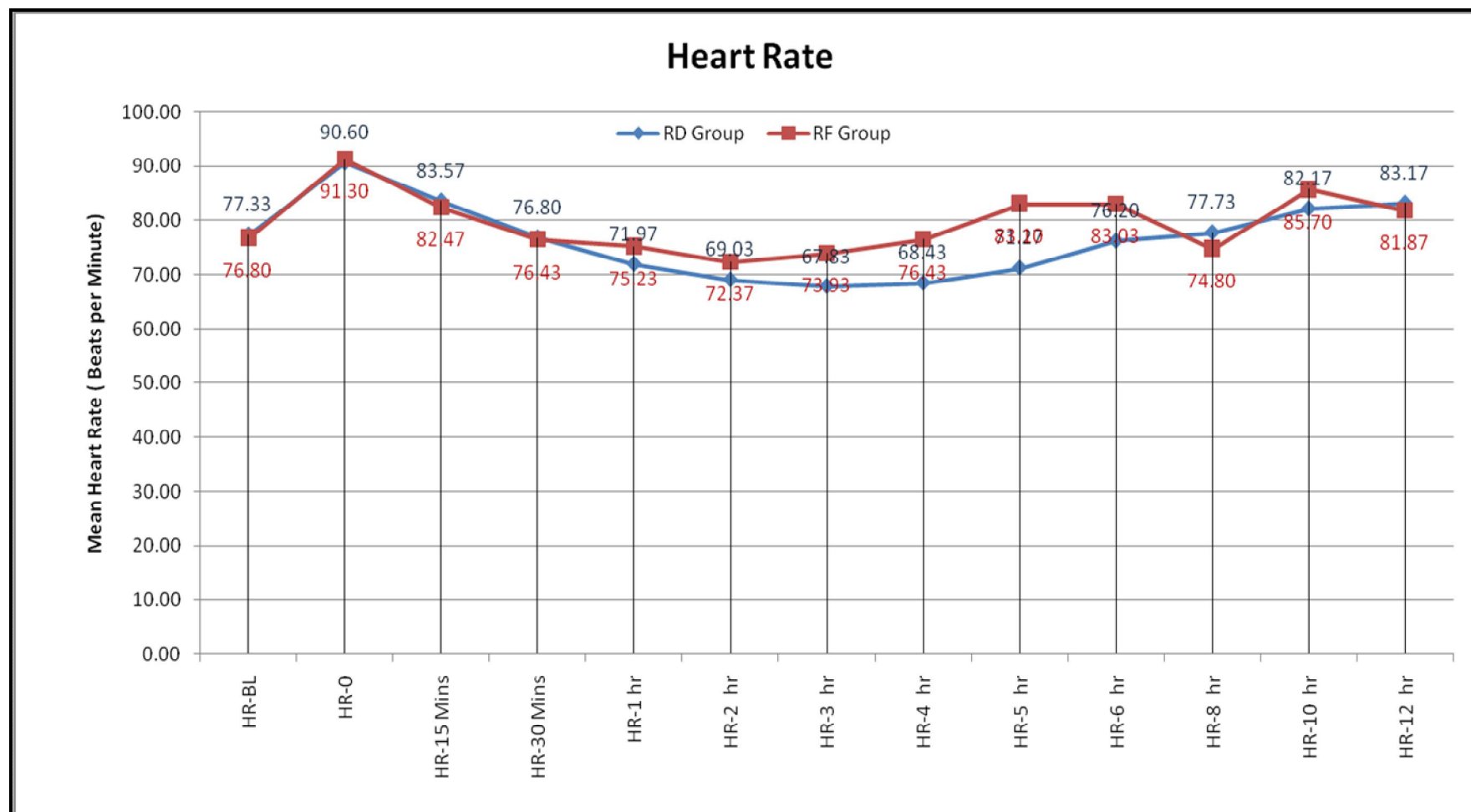
Majority of the Ropivacaine + Dexmedetomidine(RD) group patients belonged to the 5-6 hours drug duration time class interval (n=22, 73.33%) with a mean drug duration time of 5.83 hours. In the Ropivacaine + Fentanyl(RF) group patients, majority belonged to the same class interval as RD group (n=24, 80%) with a mean drug duration time of 4.97 hours. The association between the intervention groups and drug duration time distribution is considered to be statistically significant since $p < 0.05$ as per unpaired t test.

By conventional criteria the association between the intervention groups and drug duration time is considered to be statistically significant since $p < 0.05$ as per unpaired t test. In simple terms, Majority of the RD intervention group patients belonged to the 5-6 hours drug duration time class interval (n=22, 73.33%) with a mean drug duration time of 5.83 hours. In the RF group patients, majority belonged to the same class interval as RD group (n=24, 80%) with a mean drug duration time of 4.97 hours. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0003.

The mean drug duration of analgesia was meaningfully more in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean time of 52.20 minutes. This significant difference of 1.17 times increase in mean drug onset time among patients belonging to Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance. In this study we can safely conclude that Ropivacaine + Dexmedetomidine results in significantly longer duration of analgesia compared to Ropivacaine + Fentanyl when used in post-operative patients who underwent elective spine surgeries.

Table 10. Heart Rate

	Heart rate	HR-BL	HR-0	HR-15 Mins	HR-30 Mins	HR-1 hr	HR-2 hr	HR-3 hr	HR-4 hr	HR-5 hr	HR-6 hr	HR-8 hr	HR-10 hr	HR-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	77.33	90.60	83.57	76.80	71.97	69.03	67.83	68.43	71.27	76.20	77.73	82.17	83.17
	SD	5.96	7.56	6.65	6.25	6.97	8.05	8.36	8.37	8.98	9.46	6.80	7.46	6.66
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	76.80	91.30	82.47	76.43	75.23	72.37	73.93	76.43	83.10	83.03	74.80	85.70	81.87
	SD	6.93	6.78	5.14	7.14	6.82	6.40	6.79	7.52	9.56	8.80	9.98	9.72	8.34
	P value Unpaired t test	0.7505	0.7073	0.4768	0.8332	0.0716	0.0813	0.0030	0.0003	0.0000	0.0053	0.1893	0.1201	0.5076



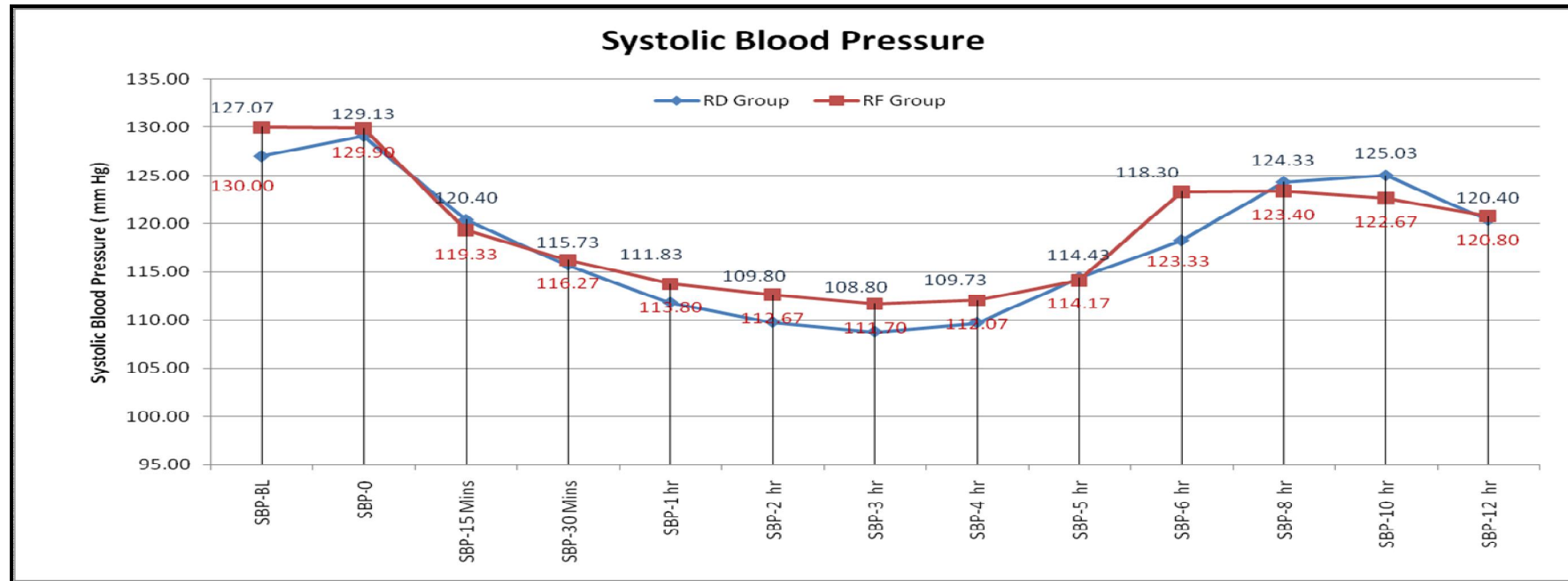
By conventional criteria the association between the intervention groups and heart rate is considered to be statistically significant between 3-6 hours since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to Ropivacaine + Dexmedetomidine intervention group, the heart rate is decreased to an average of 70.93 beat per minute in comparison with patients belonging to Ropivacaine + Fentanyl intervention group in whom the heart rate is an average of 79.13 beat per minute. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of < 0.05 according to unpaired t-test.

The heart rate was meaningfully less in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean difference of 8.19 beat per minute . This significant difference of 10% reduction in heart rate in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance.

In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmedetomidine results in significantly lower heart rate compared to Post- operative epidural block with Ropivacaine + Fentanyl when used in post-operative patients who underwent elective spine surgeries.

Table 11. Systolic Blood Pressure

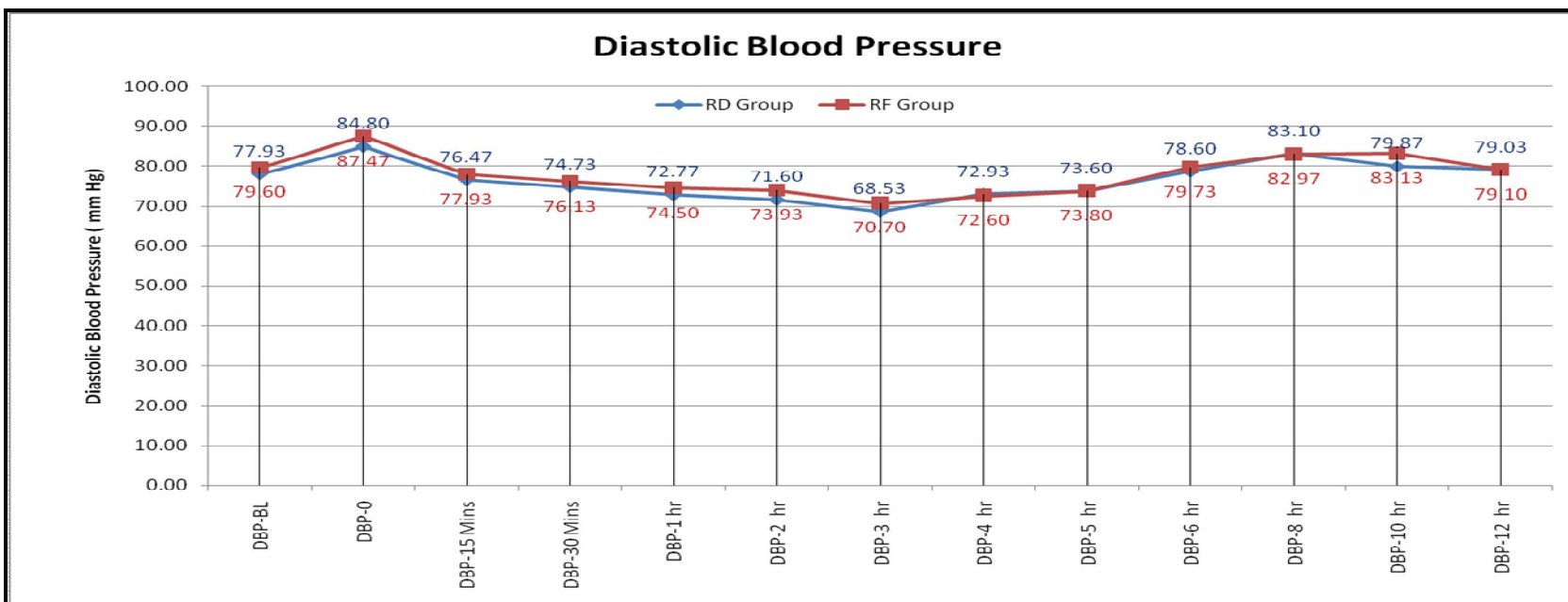
	Systolic Blood Pressure	SBP-BL	SBP-0	SBP-15 Mins	SBP-30 Mins	SBP-1 hr	SBP-2 hr	SBP-3 hr	SBP-4 hr	SBP-5 hr	SBP-6 hr	SBP-8 hr	SBP-10 hr	SBP-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	127.07	129.13	120.40	115.73	111.83	109.80	108.80	109.73	114.43	118.30	124.33	125.03	120.40
	SD	11.30	8.08	7.05	7.42	7.07	10.08	8.69	4.16	9.50	11.67	8.58	8.91	7.36
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	130.00	129.90	119.33	116.27	113.80	112.67	111.70	112.07	114.17	123.33	123.40	122.67	120.80
	SD	9.39	8.20	7.01	6.10	5.02	5.34	5.22	5.13	7.09	10.36	9.93	9.18	9.23
	P value Unpaired t test	0.2788	0.7166	0.5593	0.7622	0.2195	0.1756	0.1238	0.0581	0.9024	0.0826	0.6983	0.3150	0.8534



Most of the Ropivacaine + Dexmedetomidine intervention group patients had mean SBP ranging from 127.07 mm Hg at baseline to 120.40 mm Hg at the end of 12 hours. Similarly the Ropivacaine + Fentanyl intervention group patients had mean SBP ranging from 130.00 mm Hg at baseline to 120.80 mm Hg at the end of 12 hours. By conventional criteria the association between the intervention groups and systolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 12. Diastolic Blood Pressure

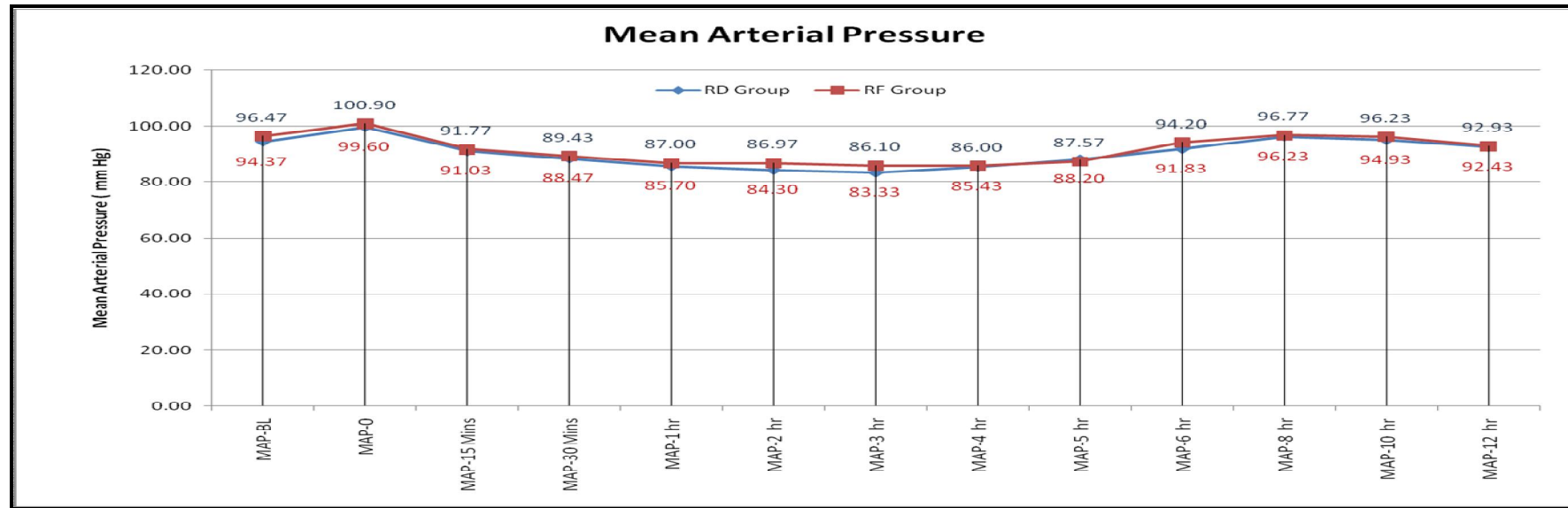
Diastolic Blood Pressure		DBP-BL	DBP-0	DBP-15 Mins	DBP-30 Mins	DBP-1 hr	DBP-2 hr	DBP-3 hr	DBP-4 hr	DBP-5 hr	DBP-6 hr	DBP-8 hr	DBP-10 hr	DBP-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	77.93	84.80	76.47	74.73	72.77	71.60	68.53	72.93	73.60	78.60	83.10	79.87	79.03
	SD	6.96	6.23	4.78	3.50	6.33	7.97	14.00	3.00	13.83	8.31	7.48	5.04	5.97
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	79.60	87.47	77.93	76.13	74.50	73.93	70.70	72.60	73.80	79.73	82.97	83.13	79.10
	SD	7.30	6.64	5.95	4.73	5.08	3.38	12.16	3.94	5.14	9.12	7.83	6.19	5.38
P value Unpaired t test		0.3691	0.1141	0.2971	0.1979	0.2474	0.1480	0.5247	0.7138	0.9412	0.6168	0.9465	0.2891	0.9639



Most of the Ropivacaine + Dexmedetomidine intervention group patients had mean DBP ranging from 77.93 mm Hg at baseline to 79.03 mm Hg at the end of 12 hours. Similarly the Ropivacaine + Fentanyl intervention group patients had mean DBP ranging from 79.60 mm Hg at baseline to 79.10 mm Hg at the end of 12 hours. By conventional criteria the association between the intervention groups and diastolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 13. Mean Arterial Pressure

	Heart rate	HR-BL	HR-0	HR-15 Mins	HR-30 Mins	HR-1 hr	HR-2 hr	HR-3 hr	HR-4 hr	HR-5 hr	HR-6 hr	HR-8 hr	HR-10 hr	HR-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	77.33	90.60	83.57	76.80	71.97	69.03	67.83	68.43	71.27	76.20	77.73	82.17	83.17
	SD	5.96	7.56	6.65	6.25	6.97	8.05	8.36	8.37	8.98	9.46	6.80	7.46	6.66
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	76.80	91.30	82.47	76.43	75.23	72.37	73.93	76.43	83.10	83.03	74.80	85.70	81.87
	SD	6.93	6.78	5.14	7.14	6.82	6.40	6.79	7.52	9.56	8.80	9.98	9.72	8.34
	P value Unpaired t test	0.7505	0.7073	0.4768	0.8332	0.0716	0.0813	0.0030	0.0003	0.0000	0.0053	0.1893	0.1201	0.5076

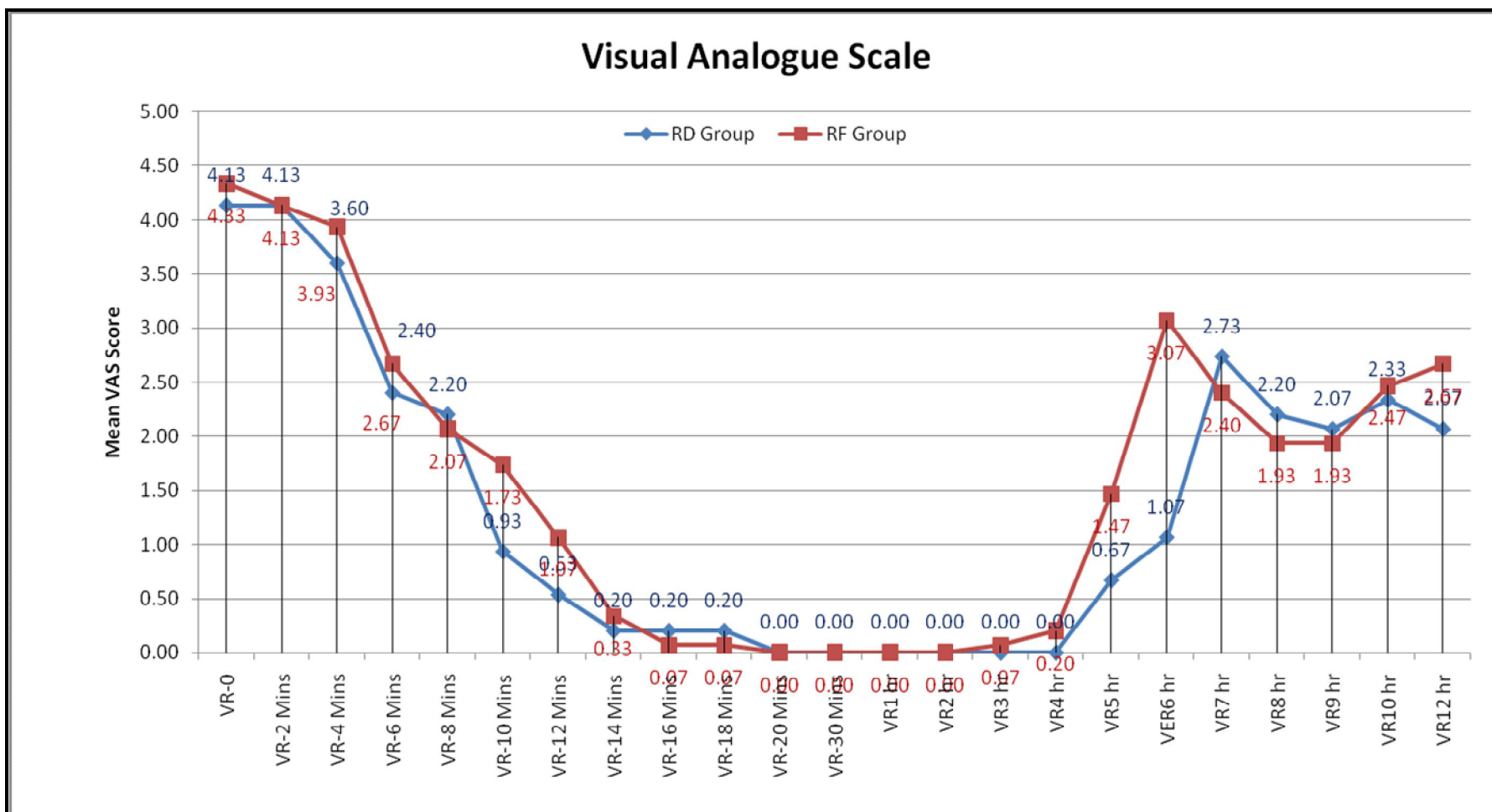


Most of the Ropivacaine + Dexmedetomidine intervention group patients had mean MAP ranging from 94.37 mm Hg at baseline to 92.43 mm Hg at the end of 12 hours. Similarly the Ropivacaine + Fentanyl intervention group patients had mean MAP ranging from 96.47 mm Hg at baseline to 92.93 mm Hg at the end of 12 hours. By conventional criteria the association between the intervention groups and mean arterial pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 14. Visual Analogue Scale

Visual Analogue Score		VR-0	VR-2 Mins	VR-4 Mins	VR-6 Mins	VR-8 Mins	VR-10 Mins	VR-12 Mins	VR-14 Mins	VR-16 Mins	VR-18 Mins	VR-20 Mins	VR-30 Mins
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	4.13	4.13	3.60	2.40	2.20	0.93	0.53	0.20	0.20	0.20	0.00	0.00
	SD	0.51	0.51	0.81	0.81	0.61	1.01	0.90	0.61	0.61	0.61	0.00	0.00
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	4.33	4.13	3.93	2.67	2.07	1.73	1.07	0.33	0.07	0.07	0.00	0.00
	SD	0.92	0.51	0.37	0.96	0.37	0.69	1.01	0.76	0.37	0.37	0.00	0.00
P value Unpaired t test		0.3036	1.0000	0.0472	0.0250	0.0309	0.0008	0.0355	0.4562	0.3097	0.3097	> 0.999	> 0.999

Visual Analogue Score		VR1 hr	VR2 hr	VR3 hr	VR4 hr	VR5 hr	VR6 hr	VR7 hr	VR8 hr	VR9 hr	VR10 hr	VR12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30
	Mean	0.00	0.00	0.00	0.00	0.67	1.07	2.73	2.20	2.07	2.33	2.07
	SD	0.00	0.00	0.00	0.00	1.60	1.64	1.53	0.81	0.37	0.76	0.37
RF Group	N	30	30	30	30	30	30	30	30	30	30	30
	Mean	0.00	0.00	0.07	0.20	1.47	3.07	2.40	1.93	1.93	2.47	2.67
	SD	0.00	0.00	0.37	0.81	1.48	1.26	0.81	0.64	0.64	0.86	0.96
P value Unpaired t test		> 0.999	> 0.999	0.3256	0.1841	0.0494	0.0000	0.2978	0.1611	0.0326	0.0268	0.0028



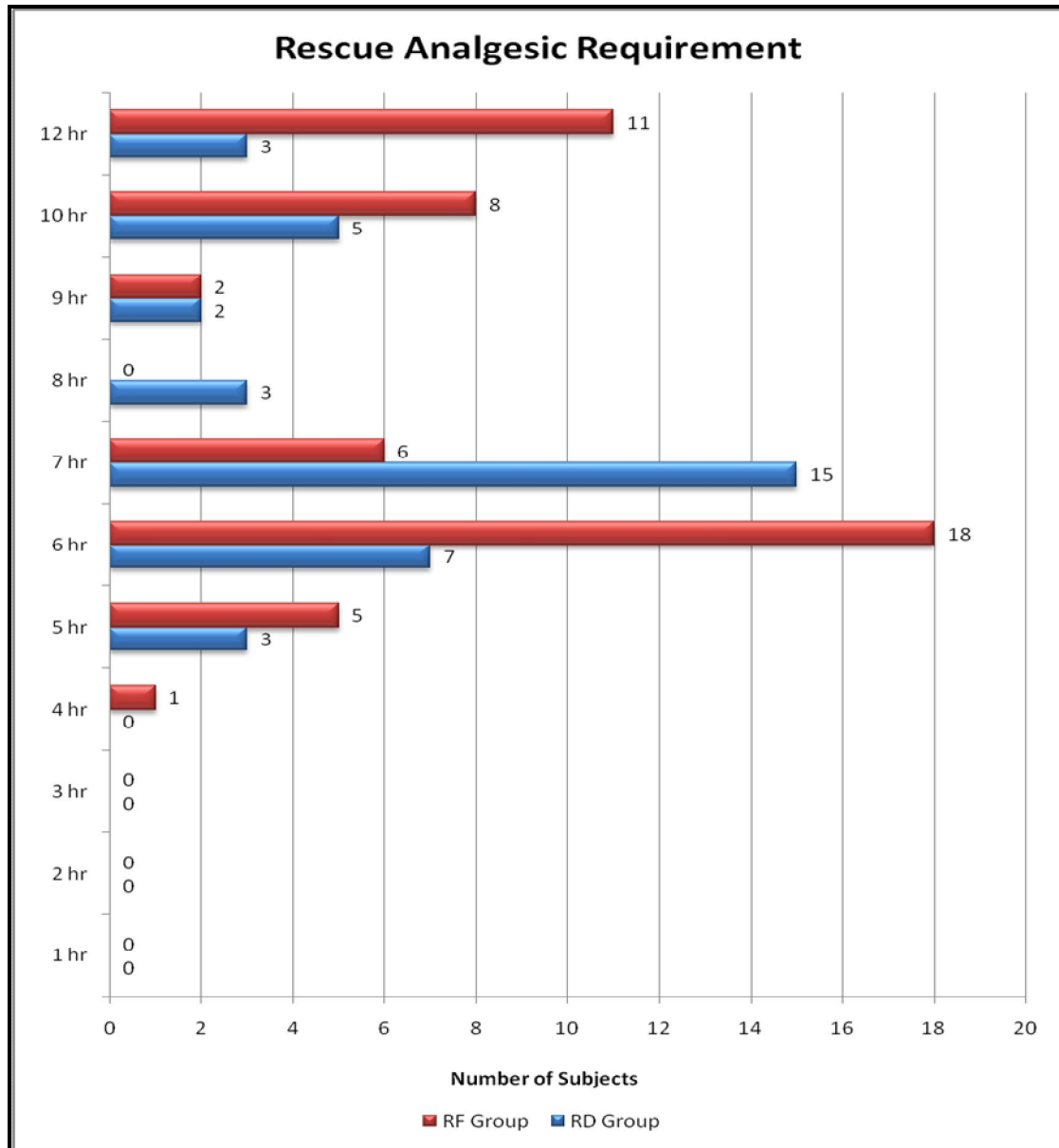
By conventional criteria the association between the intervention groups and VAS score is considered to be statistically significant between 4-12 minutes, 5-6 hours and 9-12 hours since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to Ropivacaine + Dexmedetomidine intervention group, the VAS score is decreased to an average of 1.79 in comparison with patients belonging to Ropivacaine + Fentanyl intervention group in whom the heart rate is an average of 2.31. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of < 0.05 according to unpaired t-test.

The VAS score was meaningfully less in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean difference of 0.52. This significant difference of 23% reduction in VAS score in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance.

In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmedetomidine results in significantly lowered Visual Analogue Scale score compared to Post- operative epidural block with Ropivacaine + Fentanyl when used in post-operative patients who are underwent elective spine surgeries.

Table 18. Rescue Analgesic Requirement

Rescue Analgesic Requirement	RD Group	%	RF Group	%	P value Fishers Exact Test
1 hr	0	0.00	0	0.00	>0.9999
2 hr	0	0.00	0	0.00	>0.9999
3 hr	0	0.00	0	0.00	>0.9999
4 hr	0	0.00	1	1.96	>0.9999
5 hr	3	7.89	5	9.80	0.7065
6 hr	7	18.42	18	35.29	0.0082
7 hr	15	39.47	6	11.76	0.2921
8 hr	3	7.89	0	0.00	0.2373
9 hr	2	5.26	2	3.92	1.0000
10 hr	5	13.16	8	15.69	0.5321
12 hr	3	7.89	11	21.57	0.0303
Total	38	100.00	51	88	



By conventional criteria the association between the intervention groups and rescue analgesic requirement is considered to be statistically significant at 6th, 7th and 12th hour since $p < 0.05$ as per fishers exact test. In simple terms, the rescue analgesic requirement at 6th hour was less in patients belonging to Ropivacaine + Dexmedetomidine intervention group (n=7, 18.42%) in comparison with patients belonging to Ropivacaine + Fentanyl intervention group (n=18, 35.29%) This indicates that there is a true difference among intervention groups and the difference is

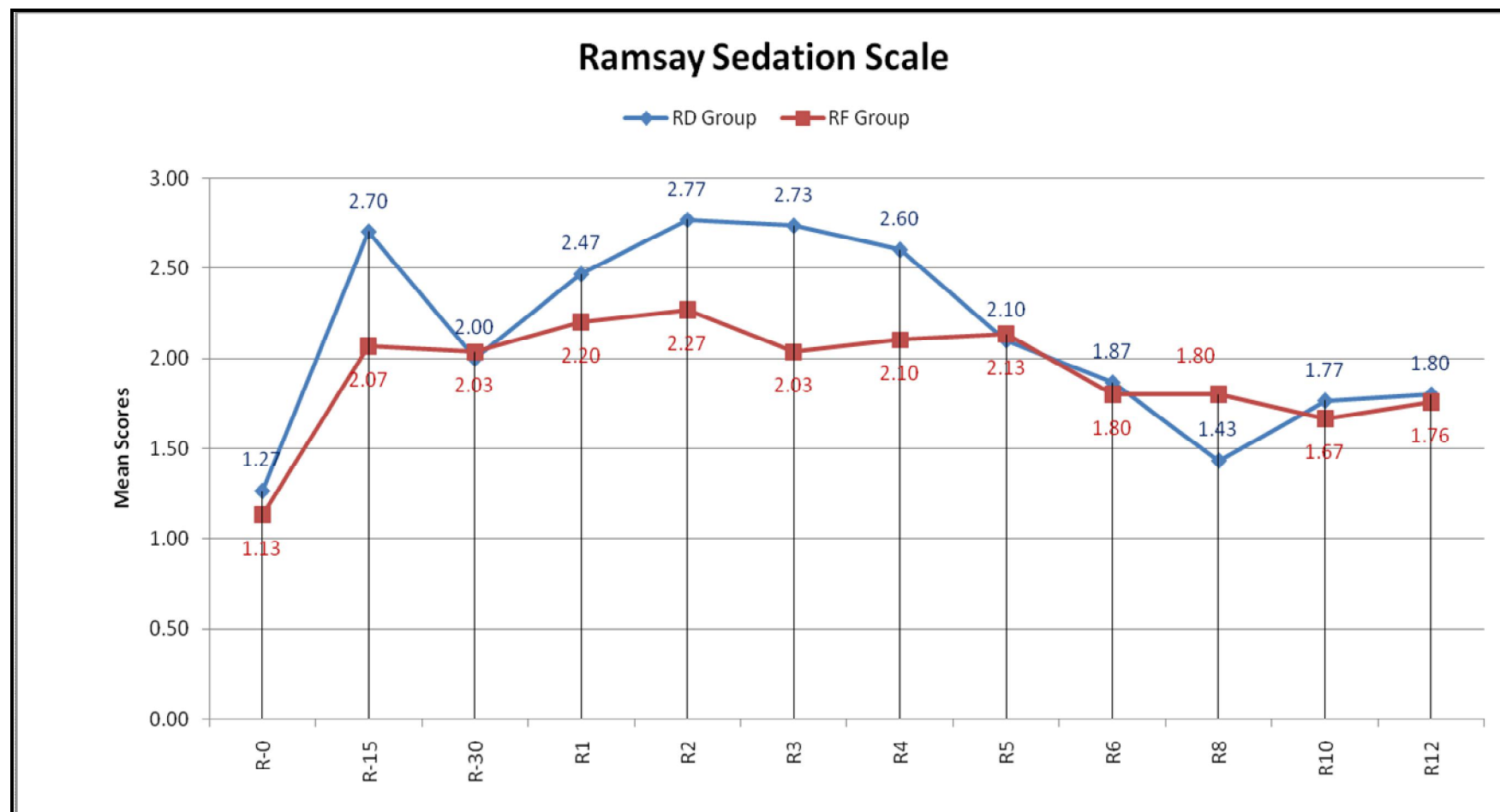
significant with a p-value of 0.0082. The rescue analgesic requirement was meaningfully less in Ropivacaine + Dexmedetomidine intervention group at 6th hour compared to Ropivacaine + Fentanyl intervention group by a difference of 16.87 percentage points. This significant difference of 1.92 times increase in the rescue analgesic requirement in Ropivacaine + Fentanyl intervention group compared to Ropivacaine + Dexmedetomidine intervention group is true and has not occurred by chance.

Similarly the rescue analgesic requirement at 12th hour was less in patients belonging to Ropivacaine + Dexmedetomidine intervention group (n=3, 7.89%) in comparison with patients belonging to Ropivacaine + Fentanyl intervention group (n=11, 21.57%). This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0303. The rescue analgesic requirement was meaningfully less in Ropivacaine + Dexmedetomidine intervention group at 12th hour compared to Ropivacaine + Fentanyl intervention group by a difference of 13.67 percentage points. This significant difference of 2.73 times increase in the rescue analgesic requirement in Ropivacaine + Fentanyl intervention group compared to Ropivacaine + Dexmedetomidine intervention group is true and has not occurred by chance.

In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmedetomidine results in significantly lower rescue analgesic requirement compared to Post- operative epidural block with Ropivacaine + Fentanyl when used in post-operative patients who are underwent elective spine surgeries.

Table 16. Ramsay Sedation Scale

	Ramsay Sedation Scale	R-0	R-15 mins	R-30 mins	R1 hr	R2 hr	R3 hr	R4 hr	R5 hr	R6 hr	R8 hr	R10 hr	R12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	1.27	2.70	2.00	2.47	2.77	2.73	2.60	2.10	1.87	1.43	1.77	1.80
	SD	0.45	3.83	0.00	0.51	0.43	0.45	0.50	0.48	0.35	0.50	0.43	0.61
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	29
	Mean	1.13	2.07	2.03	2.20	2.27	2.03	2.10	2.13	1.80	1.80	1.67	1.76
	SD	0.35	0.25	0.18	0.41	0.45	0.32	0.31	0.43	0.48	0.41	0.55	0.44
	P value Unpaired t test	0.2034	0.3740	0.3256	0.0287	0.0000	0.0000	0.0000	0.7791	0.5421	0.0030	0.4344	0.7649

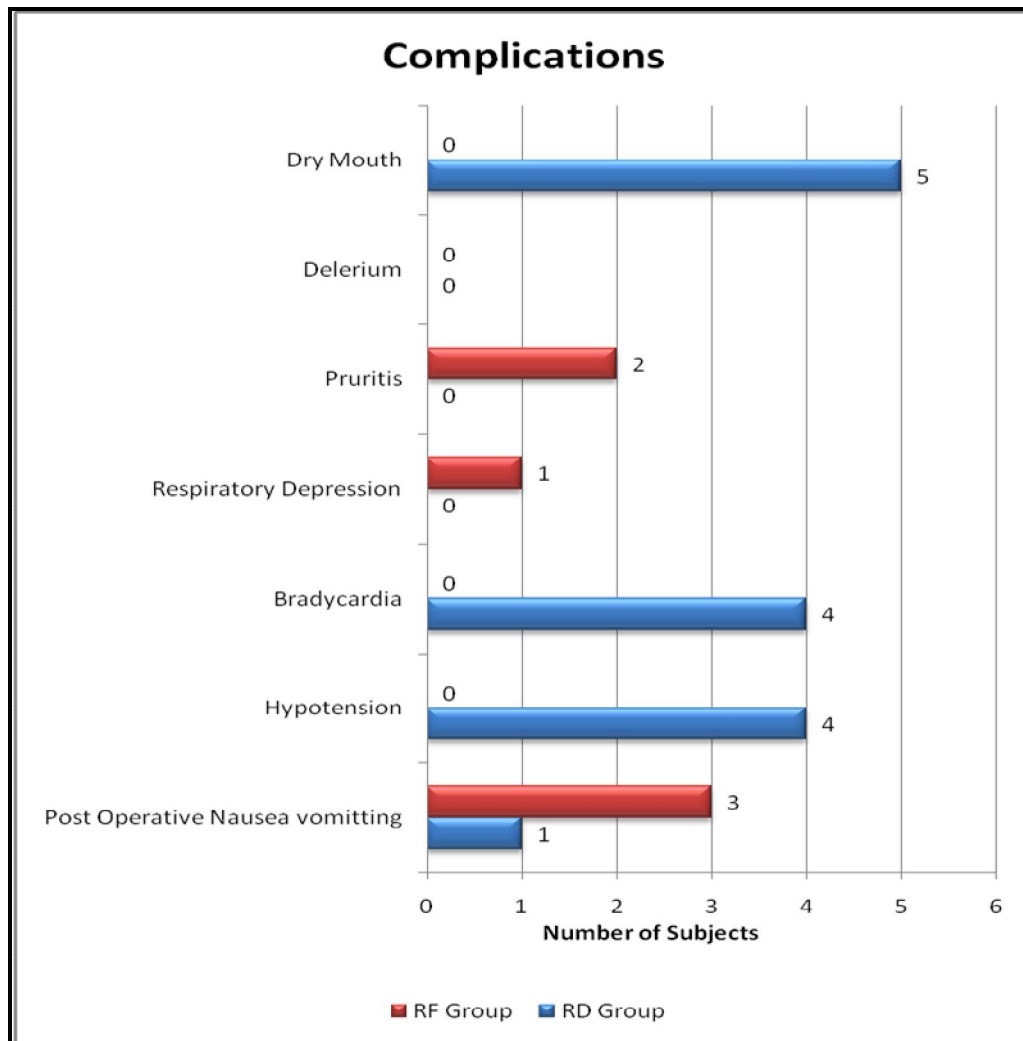


By conventional criteria the association between the intervention groups and RSS score is considered to be statistically significant between 1-4 hours and 8th hour since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to Ropivacaine + Dexmedetomidine intervention group, the RSS score is increased to an average of 2.40 in comparison with patients belonging to Ropivacaine + Fentanyl intervention group in whom the RSS score is an average of 2.08. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of < 0.05 according to unpaired t-test. The RSS score was meaningfully more in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean difference of 0.32. This significant difference of 1.15 times increase in RSS score in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance.

In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmedetomidine results in significantly higher Ramsay Sedation Scale score compared to Post- operative epidural block with Ropivacaine + Fentanyl when used in post-operative patients who underwent elective spine surgeries.

Table 17. Complications

Complications	RD Group	%	RF Group	%	p value Fishers Exact Test
Post-Operative Nausea vomiting	1	7.14	3	50.00	0.6120
Hypotension	4	28.57	0	0.00	0.0562
Bradycardia	4	28.57	0	0.00	0.0562
Respiratory Depression	0	0.00	1	16.67	>0.9999
Pruritus	0	0.00	2	33.33	0.4915
Delirium	0	0.00	0	0.00	>0.9999
Dry Mouth	5	35.71	0	0.00	0.0522
Total	14	100	6	100	



Most of the Ropivacaine + Dexmedetomidine intervention group patients had dry mouth as the presenting complication ($n=5$, 35.71%) . Similarly the Ropivacaine + Fentanyl intervention group patients had pruritis as the presenting complication ($n=2$, 33.33%). By conventional criteria the association between the intervention groups and complications is considered to be not statistically significant since $p > 0.05$ as per fishers exact test.

DISCUSSION

Patients undergoing spinal surgeries experience severe pain in the postoperative period, which may increase the morbidity , incidence of complications and prolong postoperative rehabilitation. Postoperative pain therapy mainly consists of administration of oral or intravenous opioids in combination with non steroidal anti-inflammatory drugs, but it often results in insufficient pain control and side effects such as respiratory depression, nausea, and vomiting

. Epidural anesthesia and analgesia have been shown to be superior to intravenous analgesia with respect to quality of pain relief, incidence of side effects, pulmonary, cardiac, and gastrointestinal dysfunction. Turner *et al.*⁽³⁴⁾, showed in an observational study that epidural catheters placed intraoperatively by the surgeon followed by infusion of local anesthetics with or without opioids were capable of providing good analgesia after posterior spinal fusion. Even when the epidural space was disrupted during surgery, local anesthetic that leaks out from epidural space acts like wound infiltration.

A good cooperation and communication is needed with the respective surgeon , who places the epidural catheter directly into the surgical field. It is easy to understand that surgeons are afraid of development of any kind of infection of the wound or the epidural space, especially after spine surgery, because even small hematomas are an excellent medium for bacteria. At first glance, a catheter directly placed in this area does not gain acceptance in the

eyes of the surgeons, irrespective of the applied medication. Apart from dislodgement, the placement of an epidural catheter into a recently operated area in the vertebral column with epidural application of local anesthetics may include the problem of unpredictable absorption of the drug and motor blockade.

An ideal adjuvant should provide a longer duration of analgesia and better hemodynamic stability. There is a reduced requirement of analgesics with the use of an epidural adjuvant due to the property of augmentation of the local anaesthetic effects, thereby prolonging the duration of analgesia.

To avoid neuraxial opioid induced adverse effects such as respiratory depression, nausea, vomiting, urinary retention and pruritus, α -2 agonists are being used as an alternative epidural adjuvants. Introduction of this newer agent Dexmedetomidine has increased the scope of α -2 agonists usage in neuraxial blockade. Rapid onset of local anaesthetic action, longer period of analgesia and better cardiovascular parameters have widened the scope of usage of Dexmedetomidine epidurally.

In our prospective randomized control study, we compared the analgesic efficacy of Fentanyl 1 μ g/kg and Dexmedetomidine 1 μ g/kg which were added to 15 ml 0.2% Ropivacaine, by giving these drugs through an epidural catheter in 60 patients underwent elective spine surgeries. The efficacy of Dexmedetomidine verses fentanyl as an adjuvant in epidural analgesia was studied. The patients in both the groups with respect to age, weight, ASA Physical status did not show a statistically significant difference.

ONSET OF ANALGESIA

Sukhminder jit singh bajwa *et al* ⁽¹⁹⁾., did a comparative study in 100 patients who underwent elective lower limb orthopaedic surgeries under lumbar epidural with Dexmedetomidine 1µg/kg and Fentanyl 1µg/kg added to Ropivacaine 0.75% as the study drug. In that study the onset time to reach T10 sensory level, was significantly shorter in group RD (7.12 ±2.44min.) as compared to group RF(9.146±2.94).

MS Saravana babu *et al.*, (2014)⁽⁶⁾ conducted a prospective randomized study in 60 patients to evaluate the efficacy and clinical profile of Dexmedetomidine and Clonidine as an adjuvant to Ropivacaine, in epidural analgesia in spine surgeries by giving 20 ml of 0.2% Ropivacaine and 1 µg/kg of Dexmedetomidine (group RD) or 20 ml of 0.2% Ropivacaine and 2 µg/kg of Clonidine (group RC). They observed that the addition of Dexmedetomidine to Ropivacaine as an adjuvant resulted in an earlier onset (7.33±1.76 min) of analgesia as compared to the addition of Clonidine (8.40±1.61 min).

Ajay Kumar Anandan *et al.*, (2014)⁽³⁰⁾ conducted a study comparing Ropivacaine with Dexmedetomidine (RD) with Ropivacaine (R) in 30 patients and concluded that the onset was earlier in RD (3.60min.) compared with R group (4.60 min.).

In our study the onset of sensory analgesia was earlier in the RD group (5.93 ± 0.700 min) than in the RF group (7.67 ± 0.702 min). For onset of anaesthesia, the determinants are, diffusion through meningeal layers, penetration of neural tissue and distribution of the drug in various tissues. Dexmedetomidine being more lipophilic and having a favorable pKa produces an earlier onset of analgesia than fentanyl.

PEAK EFFECT OF ANALGESIA

In **Sukhminder jit singh bajwa *et al*** comparative study the time to reach peak analgesia was significantly shorter in RD group (13.38 ± 4.48) compared to RF group (16.61 ± 4.36)

The peak effect of analgesia in our study was at 12.07min. for RD group and at 13.13min. for RF group which is statistically not significant (Pvalue-0.1330) in our study.

DURATION OF ANALGESIA

In **Sukhminder jit singh bajwa *et al*** ⁽¹⁹⁾ comparative study the mean duration of analgesia was longer (366.62 ± 24.42 min) in RD group than (242.16 ± 3.86 min) in the RF group thus promising the superior block characteristics of RD group than RF group

In the study conducted by **MS Saravana babu *et al.***, (2014) the duration of analgesia was also prolonged in Dexmedetomidine group (407.00 ± 47.06 min) compared to Clonidine group (345.01 ± 35.02).

Mausumi Neogi *et al.*, ⁽²⁴⁾ (2010) did a comparative study on paediatric patients undergoing elective inguinal herniotomy. They compared the efficacy of Clonidine $1 \mu\text{g/kg}$ and Dexmedetomidine $1 \mu\text{g/kg}$ as adjuvants to Ropivacaine for caudal analgesia.. They randomized the patients into 3 study groups, group R (Ropivacaine), group C (Ropivacaine + Clonidine), group D (Ropivacaine + Dexmedetomidine) and observed that, the mean duration of analgesia was 6.32 ± 0.46 hours in group R, 13.17 ± 0.68 hours in group C and 15.26 ± 0.86 hours in group D. . They concluded that the addition of both Clonidine and Dexmedetomidine with Ropivacaine administered caudally significantly increased the duration of analgesia

In **Ajay Kumar Anandan *et al.***,⁽³⁰⁾ (2014) study comparing Ropivacaine with Dexmedetomidine (RD) with Ropivacaine (R) in 30 patients and concluded that the duration of analgesia was prolonged in RD (289min.) compared to R group (243 min). this results were correlated with our study.

Sarabjit Kaur *et al.*,⁽³³⁾ (2014) conducted a prospective, randomized double-blind study in 100 patients undergoing lower limb surgeries by randomly into groups receiving 150 mg of 0.75% Ropivacaine (Group A) and 150 mg of 0.75% Ropivacaine with Dexmedetomidine ($1 \mu\text{g/kg}$) (Group B). Two groups were compared with hemodynamic changes,

block characteristics which included time to onset of analgesia at T10, maximum sensory analgesic level, time to maximum sensory and motor block, regression at S1 dermatome and time to the first dose of rescue analgesia. Significant difference was observed in relation to the duration of sensory block (375.20 ± 15.97 min. in Group A and 535.18 ± 19.85 min. in Group B [$P = 0.000$]), duration of motor block (259.80 ± 15.48 min in Group A and 385.92 ± 17.71 min in Group B [$P = 0.000$]), duration of post-operative analgesia (312.64 ± 16.21 min in Group A and 496.56 ± 16.08 min in Group B [$P < 0.001$]) and consequently low doses of rescue analgesia in Group B (1.44 ± 0.501) as compared to Group A (2.56 ± 0.67). They concluded that Epidural Dexmedetomidine as an adjuvant to Ropivacaine associated with prolonged sensory and motor block, hemodynamic stability, prolonged postoperative analgesia and reduced demand for rescue analgesics when compared to plain Ropivacaine. These study also concluded that addition of Dexmedetomidine to Epidural Ropivacaine prolongs the duration of action, and gives earlier onset of action of Ropivacaine.

Ravi Prakash, B.B.Kushwaha, Shashibhushan, V.K.Bhatia, Girish Chandra and B.P.Singh et al did a comparative study of Bupivacaine 0.25% alone and with Fentanyl or Dexmedetomidine for percutaneous nephrolithotomy (pcnl) under epidural anaesthesia. The study was conducted on 75 patients who were randomly allocated in to three groups, Group A (n=25): patient receiving only 20 ml epidural 0.25% Bupivacaine. Group B (n=25): patient receiving 20 ml epidural 0.25% Bupivacaine along with Fentanyl (1mcg/kg) and Group C (n=25): patient

receiving 20 ml epidural 0.25% Bupivacaine along with Dexmedetomidine (1mcg/kg). They observed that addition of Fentanyl and Dexmedetomidine prolongs the duration of analgesia. Dexmedetomidine was more effective in this respect. Time for 2 segment regression was 86.52 ± 9.07 minutes for Group A, 120.00 ± 5.95 minutes for Group B and 135.40 ± 9.57 minutes for Group C.

In our study, the mean duration of analgesia as measured by the time taken for first rescue analgesic was significantly longer in RD group than RF group (349.80 ± 8.124 min vs 298.20 ± 4.77 min). The mean duration time was meaningfully more in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean time of 52.20 minutes. This parameter shows that the analgesic potentiating effect of Dexmedetomidine is more than that of Fentanyl.

HAEMODYNAMIC PARAMETERS.

The study done by **Sukhminder jit singh bajwa** et al⁽¹⁹⁾., showed hemodynamic stability with both RF and RD groups and there was no significant difference on statistical comparison. The mean dose of Mephentermine required was 11.8mg in RD and 8mg in RF group in their study

The better hemodynamic stability and longer duration of sensory analgesia by dexmedetomidine has also been shown in the study of **Gupta et al⁽²⁶⁾**. They compared intrathecal administration of ropivacaine and ropivacaine/ dexmedetomidine and concluded that dexmedetomidine group has longer duration of analgesia with better hemodynamic stability.

In A comparative study in the post-operative spine surgeries by epidural Ropivacaine with Dexmedetomidine and Ropivacaine with Clonidine for post-operative analgesia conducted by **M S.Saranababu** et al there was no significant difference of heart rate and mean arterial blood pressure in both the groups at the time of administration of drugs, but it started to decrease as evident at 30 min post-injection, there was a fall in both groups. There was a decreasing trend of heart rate and mean arterial pressure post-injection in both groups and this decrease was significant in the RC group compared with RD group ($P < 0.05$) but none of the patient showed bradycardia or hypotension at any time. There was a decrease in mean respiratory rate in both the groups after giving the drug and the difference between the groups was statistically not significant ($P > 0.05$) at different time intervals. None of the patient showed respiratory depression ($< 10/\text{min}$) at any time

In our study the mean Heart Rate(HR), Systolic blood pressure (SBP), Diastolic blood pressure(DBP) at varying time intervals showed significant difference between the groups RD and RF. Though there was decrease in HR, fall in SBP, DBP in both the groups, the mean HR was maintained between 60-70/min (70.93) in RD group whereas it was maintained at 65-80/min(79.13) in RF group. The mean SBP range from 127.07 mm Hg at

baseline to 120.40 mm Hg at the end of 12 hours in RD group and mean SBP ranging from 130.00 mm Hg at baseline to 120.80 mm Hg at the end of 12 hours in RF group. The mean DBP range from 77.93 mm Hg at baseline to 79.03 mm Hg at the end of 12 hours in RD group and mean DBP range from 79.60 mm Hg at baseline to 79.10 mm Hg at the end of 12 hours in RF group.

VISUAL ANALOGUE SCORE

VAS score between group RD was 1.79 and 2.31 in group RF and found to be significant during the whole period of observation ($p < 0.05$) which correlated with study done by **Gupta et al** ⁽²⁶⁾., which showed the maximum visual analogue scale score for pain was less in group RD (4.4 ± 1.4) as compared to group R (6.8 ± 2.2)

RESCUE ANALGESIC REQUIREMENT%).

In the study conducted by **Sarabjit kaur et al.**,⁽²⁵⁾ there was significant delayed requirement of rescue analgesia (496.56 ± 16.08 min in Group A and 312.64 ± 16.21 min in Group B) and also reduced 24 h analgesic requirement (1.44 ± 0.501 in Group B and 2.56 ± 0.67 in Group A) with $1\mu/\text{kg}$ Dexmedetomidine added to Ropivacaine, which supports the analgesic efficacy of Dexmedetomidine as an epidural adjuvant.

In the study conducted by **MS Saravana babu et al.**, (2014)⁽³²⁾, they compared the efficacy of Ropivacaine and Dexmedetomidine with Ropivacaine and Clonidine. They concluded that the need for IV rescue analgesics in both the groups was nil throughout the study period. The mean VAS score was higher in the Clonidine group at each time interval. They

concluded that, the epidural route provided adequate analgesia in spine surgeries and Dexmedetomidine is a better neuraxial adjuvant to Ropivacaine for providing early onset and prolonged post-operative analgesia and stable cardiorespiratory parameters

In our study, the rescue analgesic requirement at the 6th hour was less in RD group(18.42%) compared to RF group (35.29%) . Similarly at 12th hour, it was 7.89% in RD group compared to RF group (21.57 early onset and prolonged post-operative analgesia and stable cardio respiratory parameters.

RAMSAY SEDATION SCORE (RSS)

The study conducted by **Sukhminder jit singh bajwa et al.**⁽¹⁹⁾, showed that sedation in RDgroup was 2 in 38% , 3 in 48% whereas RF group had sedation score of 2 in 16% and 3 in 2%. in this study we can safely conclude that RSS score was significantly higher in RD group than RF group

Oriol-Lopez et al⁽²⁴⁾ conducted an observational study to find out the anxiolytic and sedative property of dexmedetomidine. Epidural dexmedetomidine 1µg/kg was given with lignocaine in 40 patients who underwent various abdominal surgeries. They used Ramsay sedation score and concluded that 90% of the study group were sedated to a score of 3 and 4 from 15 to 90 minutes after drug administration.

In our study, the mean sedation score at various time intervals was significant between these two groups. Majority of patients in RF group were sedated to score of 0,1 and 2 but in RD group the patients were sedated to a score of 2 and 3.

COMPLICATIONS

Sukhminder jit singh bajwa et al.⁽¹⁹⁾, showed nausea and vomiting as the predominant side effect in RF group, nausea and dry mouth in RD group and none in both the groups had respiratory depression.

In our study, the predominant side effect was dry mouth , bradycardia and hypotension in RD group whereas in RF group it was Nausea and vomiting. In the RD group, 35.71% had dry mouth, bradycardia and hypotension 28%. Similarly the RF group 50% had Nausea and vomiting pruritis 33% as the presenting complication. There was no respiratory depression in RD group but 16.67% in RF group.

SUMMARY

In this prospective randomized study, the analgesic efficacy of Dexmedetomidine 1µg/kg and Fentanyl 1µg/kg which were added to 15 ml of 0.2% Ropivacaine were compared by giving these drugs through an epidural catheter in 60 patients undergoing elective spine surgeries. The efficacy of Dexmedetomidine versus Fentanyl as an adjuvant in epidural analgesia was studied.

The following observations were made:

- 1) The onset of sensory analgesia was earlier in Ropivacaine Dexmedetomidine (RD) group (5.93 ± 0.700 min) than Ropivacaine Fentanyl (RF) group (7.67 ± 0.702 min).
- 2) The peak effect of analgesia in our study was 12.07min. for RD group and 13.13min. for RF group which is statistically significant (Pvalue-0.1330).
- 3) The mean duration of analgesia as measured by the time taken for first rescue analgesic was significantly longer in RD group than RF group (349.80 ± 8.124 min vs 298.20 ± 4.77 min).
- 4) Both the groups showed haemodynamic stability but the incidence of side effects such as hypotension and bradycardia were more in patients who received Dexmedetomidine, which was managed easily with inj Ephedrine 6mg and inj Atropine 0.6 mg.

- 5) Visual Analogue Scale score in group RD was 1.79 and 2.31 in group RF and it was found to be significant during the whole period of observation ($p < 0.05$)
- 6) The rescue analgesic requirement was less with RD group when compared to RF group in the whole study period.
- 7) The administration of Dexmedetomidine epidurally produced sedation that was arousable, for many hours when compared to the plain Ropivacaine group. The mean sedation score at various time intervals was significant between these two groups.
- 8) No episode of respiratory depression was noted in RD group compared to RF group.

CONCLUSION

It can be concluded from this study that epidural route provided adequate effective analgesia in spine surgeries in terms of VAS score in both the groups. However, Dexmedetomidine seems to be a better alternative to Fentanyl as an epidural adjuvant as it provides comparable , early onset and establishment of sensory anaesthesia, prolonged analgesia in the post operative period, lesser consumption of post-operative rescue analgesics, stable haemodynamics and much better sedation levels.

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INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.M.Bhaskar
Postgraduate M.D.(Anaesthesiology)
Madras Medical College
Chennai 600 003

Dear Dr.M.Bhaskar,


The Institutional Ethics Committee has considered your request and approved your study titled **"A prospective, randomised study comparing epidural ropivacaine and dexmedetomidine with epidural ropivacaine and fentanyl in post operative patients who are undergoing elective spine surgeries" No.01022015.**

The following members of Ethics Committee were present in the meeting held on 03.02.2015 conducted at Madras Medical College, Chennai-3.

- | | |
|--|----------------------|
| 1. Dr.C.Rajendran, M.D., | : Chairperson |
| 2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3 | : Deputy Chairperson |
| 3. Dr.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3 | : Member Secretary |
| 4. Dr.R.Nandini, M.D., Inst.of Pharmacology, MMC | : Member |
| 5. Dr.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC | : Member |
| 6. Dr.Md.Ali, M.D., D.M., Prof. & HOD of Medl.G.E., MMC | : Member |
| 7. Dr.K.Ramadevi, Director, Inst.of Biochemistry, MMC | : Member |
| 8. Dr.Saraswathy, M.D., Director, Pathology, MMC, Ch-3 | : Member |
| 9. Dr.S.G.Sivachidambaram, M.D., Director i/c
Institute of Internal Medicine, MMC, Ch-3 | : Member |
| 10. Thiru S.Rameshkumar | : Lay Person |
| 11. Thiru S.Govindasamy, B.A., B.L., | : Lawyer |
| 12. Tmt.Arnold Saulina, M.A., MSW., | : Social Scientist |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.


MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

INFORMATION TO PARTICIPENTS

Investigator : Dr. M. BHASKAR

Name of the Participant :

Title : A Prospective, randomized study comparing the efficacy and clinical profile of Dexmedetomidine and Fentanyl as an adjuvant to epidural Ropivacaine for post- operative pain relief in spine surgeries

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria. We want to compare and study the safety & efficacy of epidural block using Ropivacaine and Dexmedetomidine with Ropivacaine and Fentanyl.

What is the Purpose of the Research:

For spine surgeries, epidural block with either Ropivacaine and Dexmedetomidine or Ropivacaine and Fentanyl is given in post operative period via intra operatively placed epidural catheter. This study is done to compare the epidural block using the above mentioned drugs in patients who undergoing spine surgeries, with respect to, Onset of analgesia, Time of peak onset of analgesia and duration of analgesia, The need of rescue analgesics. Post-operative haemodynamics.

The Study Design:

All the patients in the study will be divided into two groups.

Group1- post- operative epidural block with Ropivacaine and Dexmedetomidine.

Group 2- post- operative epidural block with Ropivacaine Fentanyl.

Benefits

The epidural block provide adequate analgesia in spine surgeries in terms of VAS score and overall patient satisfaction and It avoids the need of IV/IM analgesics in post operative period in both groups. In post operative period provides stable haemodynamics . Problems associated with pain are avoided.

Discomforts and risks

There is no discomfort during block since the catheter is placed during intra operative period. Hypotension ,bradycardia may occur – emergency drugs are readily available. Vomiting and sedation may occur. Since the drug will be given based on the calculated maximum allowable dose the complication of seizures does not occur.

This intervention has been shown to be well tolerated as shown by previous studies. And if you do not want to participate you will have alternative of setting the standard treatment and your safety is our prime concern.

Time :

Date :

Place :

Signature / Thumb Impression of Patient

Patient Name:

Signature of the Investigator : _____

Name of the Investigator : _____

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

குழு மயக்கம் கொடுத்து, குழு தண்டுவுட அறுவை சிகிச்சை செய்த பின்பு, டெக்ஸ்மெடிடோமெடின் மற்றும் ஃபென்டனில் மருந்துகளை துணை மருந்தாக ரோபிவேகைன் என்ற மருந்துடன் கலந்து இவ்விடைவெளி மயக்கமருந்தாக (Epidural Analgesia) கொடுக்கும் போது ஏற்படும் வலி நிவாரண பான்களை ஒப்பிடுதல்.

ஆராய்ச்சியாளரின் பெயர் : மரு.ம.பாஸ்கர்

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம்

இவ்வாராய்ச்சியில் டெக்ஸ்மெடிடோமெடின் மற்றும் ஃபென்டனில் மருந்துகளை துணை மருந்தாக ரோபிவேகைன் என்ற மருந்துடன் கலந்து இவ்விடைவெளி வழியாக கொடுப்பதால்,

1. அறுவை சிகிச்சைக்கு பின்பு ஏற்படும் வலி நிவாரண பான்கள் மற்றும்
2. மீட்பு வலி நிவாரண மருந்துகளின் (Rescue Analgesics) தேவை இவைகளை ஒப்பிடுதல்.

ஆய்வின் தன்மை

பங்குபெறும் நோயாளிகள் இரண்டு குழுக்களாக பிரிக்கப்படுவர்.

குழு-1: ரோபிவேகைன் மற்றும் டெக்ஸ்மெடிடோமெடின் பெறும் குழு

குழு-2: ரோபிவேகைன் மற்றும் ஃபென்டனில் மருந்து பெறும் குழு

இவ்விடைவெளி வழியாக மருந்துகளை கொடுத்த பின்பு,

1. வலி எப்போது குறைய ஆரம்பிக்கிறது என்பதும், எவ்வளவு நேரம் வலி நிவாரணம் இருக்கிறது என்பது பற்றியும் ஆராயப்படுகிறது.
2. நாடித்துடிப்பு, இரத்த அழுத்தம் இவற்றின் மாற்றங்கள் கண்காணிக்கப்படுகிறது.

ஆய்வினால் ஏற்படும் நன்மைகள்:

இவ்விடைவெளி வழியாக இம்மருந்துகளை கொடுப்பதால்

1. தரமான வலி நிவாரணம் அளிக்கப்படுகிறது.
2. மீட்பு வலி நிவாரண மருந்துகளின் தேவை மற்றும் அவற்றின் பக்கவிளைவுகள் தவிர்க்கப்படுகின்றன.

உபாதைகள்:

நாடித்துடிப்பு மற்றும் இரத்த அழுத்தம் இவற்றில் மாற்றங்கள் ஏற்படலாம். அவ்வாறு ஏற்பட்டால் அந்த பக்கவிளைவுகளை எதிர்கொள்ள தேவையான மருத்துவ உபகரணங்கள் மற்றும் மருந்துகள் தயார் நிலையில் உள்ளன.

நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விருப்பப்படவில்லை என்றால் எப்போதும் உபயோகப்படுத்தப்படும் முறையில் மருந்து கொடுக்கப்படும். உங்கள் பாதுகாப்பை எங்களின் முக்கிய நோக்கம்.

சாட்சியின் கையொப்பம்

பெயர்:

நாள் :

இடம் :

பங்கேற்பாளர் கையொப்பம்

இடது கட்டைவிரல் ரேகை

பெயர்:

நாள் :

இடம் :

PATIENT CONSENT FORM

Title : A Prospective, randomized study comparing the efficacy and clinical profile of Dexmedetomidine and Fentanyl as an adjuvant to epidural Ropivacaine for post- operative pain relief in spine surgeries

Study centre: Institute of Anaesthesiology and Critical Care,
Rajiv Gandhi Govt. General Hospital, Madras Medical College, Chennai-3.

Participant Name :

Age/Sex:

I.P.No:

I confirm that I have understood the purpose of procedure for the above study . I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator , regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study . I understand that my identity will not be revealed in any information released to third parties or published , unless as required under the law . I agree not to restrict the use of any data or results that arise from the study .

Signature / thumb impression of patient

Time:

Date:

Place:

Patient Name:

Signature of the investigator:

Name of the investigator:

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

மூல மயக்கம் கொடுத்து, மூல தண்டுடன் அறுவை சிகிச்சை செய்த பின்பு, டெக்ஸ்மெடிடோமெடின் மற்றும் ஃபென்டனில் மருந்துகளை துணை மருந்தாக ரோபிவேகைன் என்ற மருந்துடன் கலந்து இவ்விடைவெளி மயக்கமருந்தாக (Epidural Analgesia) கொடுக்கும் போது ஏற்படும் வலி நிவாரண பலன்களை ஒப்பிடுதல்.

ஆராய்ச்சியாளரின் பெயர் : மரு.ம.பாஸ்கர்

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம்

இவ்வாராய்ச்சியில் டெக்ஸ்மெடிடோமெடின் மற்றும் ஃபென்டனில் மருந்துகளை துணை மருந்தாக ரோபிவேகைன் என்ற மருந்துடன் கலந்து இவ்விடைவெளி வழியாக கொடுப்பதால்,

1. அறுவை சிகிச்சைக்கு பின்பு ஏற்படும் வலி நிவாரண பலன்கள் மற்றும்
2. மீட்பு வலி நிவாரண மருந்துகளின் (Rescue Analgesics) தேவை இவைகளை ஒப்பிடுதல்.

ஆய்வின் தன்மை

பங்குபெறும் நோயாளிகள் இரண்டு குழுக்களாக பிரிக்கப்படுவர்.

குழு-1: ரோபிவேகைன் மற்றும் டெக்ஸ்மெடிடோமெடின் பெறும் குழு

குழு-2: ரோபிவேகைன் மற்றும் ஃபென்டனில் மருந்து பெறும் குழு

இவ்விடைவெளி வழியாக மருந்துகளை கொடுத்த பின்பு,

1. வலி எப்போது குறைய ஆரம்பிக்கிறது என்பதும், எவ்வளவு நேரம் வலி நிவாரணம் இருக்கிறது என்பது பற்றியும் ஆராயப்படுகிறது.
2. நாடித்துடிப்பு, இரத்த அழுத்தம் இவற்றின் மாற்றங்கள் கண்காணிக்கப்படுகிறது.

ஆய்வினால் ஏற்படும் நன்மைகள்:

இவ்விடைவெளி வழியாக இம்மருந்துகளை கொடுப்பதால்

1. தரமான வலி நிவாரணம் அளிக்கப்படுகிறது.
2. மீட்பு வலி நிவாரண மருந்துகளின் தேவை மற்றும் அவற்றின் பக்கவிளைவுகள் தவிர்க்கப்படுகின்றன.

உபாதைகள்:

நாடித்துடிப்பு மற்றும் இரத்த அழுத்தம் இவற்றில் மாற்றங்கள் ஏற்படலாம். அவ்வாறு ஏற்பட்டால் அந்த பக்கவிளைவுகளை எதிர்கொள்ள தேவையான மருத்துவ உபகரணங்கள் மற்றும் மருந்துகள் தயார் நிலையில் உள்ளன.

நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விருப்பப்படவில்லை என்றால் எப்போதும் உபயோகப்படுத்தப்படும் முறையில் மருந்து கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்களின் முக்கிய நோக்கம்.

சாட்சியின் கையொப்பம்

பெயர்:

நாள் :

இடம் :

பங்கேற்பாளர் கையொப்பம்

இடது கட்டைவிரல் ரேகை

பெயர்:

PROFORMA

Date:

Roll No:

Name:

Age/Sex:

IP No:

Diagnosis

Surgical Procedure Done

Ht:

CVS:

HB:

Wt:

RS:

Airway:

MMS:

TMD, IID:

Dentition:

Pre Op Assessment

History: Any co-morbid illness

H/o. Previous surgeries

Measures of Study outcome

HR SBP DBP MAP SPO2

Pre OP

Intraoperative Vital Signs

Dose of Opioid Used

Complications in intra operative period

Complications in post extubation Period

BY INTRAOPERATIVELY PLACED EPIDURAL CATHETERPATIENT
OUTCOME MEASURES

Time (min)	VAS	Pulse Rate	Systolic BP	Diastolic BP	SPO ₂	RR	Side Effects (Tick)
0							<div><input type="checkbox"/> Nausea</div> <div><input type="checkbox"/> Vomiting</div> <div><input type="checkbox"/> SPO₂ ↓</div> <div><input type="checkbox"/> Motor Blockade</div> <div><input type="checkbox"/> Deep Sedation</div> <div><input type="checkbox"/> Shivering</div> <div><input type="checkbox"/> Hypotension</div> <div><input type="checkbox"/> Requirement of rescue Analgesics</div>
2							
4							
6							
10							
12							
14							
16							
18							
20							
22							
24							
26							
28							
30							
60 (1Hr)							
90							
120 (2Hr)							
150							
180 (3Hr)							
210							
240 (4Hr)							
270							
300 (5Hr)							
330							
360 (6Hr)							
390							
420 (7Hr)							
450							
480 (8Hr)							
510							
540 (9Hr)							
570							
600 (10Hr)							
720(12 Hr)							

S. NO.	NAME	AGE	SEX	WEIGHT	DIAGNOSIS	SURGERY	ASA	GROUP	TIME OF ADMIN AFTER SURGERY	DRUG			HEART RATE									
										ONSET MIN	PEAK MIN	DURATION HRS	HR-BL	HR-0	HR-15 M	HR-30 M	HR-1	HR-2	HR-3	HR-4	HR-5	
1	KANNAMMAL	49	2	60	L3 L4, L4 L5 spondylolisthesis	Posterior Stabilization	1	1	20	6	14	6	77	100	86	80	82	86	84	84	86	
2	PUNITHA	40	2	64	L4 L5 disc prolapse with	Laminectomy andDiscectomy	1	1	15	8	14	6	80	94	84	80	80	77	76	80	77	
3	RAJINI	23	1	66	L2 L3 disc disease	Laminectomy discectomy	1	1	15	4	10	6	82	102	94	90	90	88	86	84	80	
4	SELVARAJ	50	1	70	L3 L4disc disease	Laminectomy + post stabilization	2	1	15	6	14	8	64	82	78	70	68	60	60	54	54	
5	ALAMELLAMMA	48	2	80	L4 L5 disc disease	Discectomy + post stabilization	2	1	10	10	20	4	70	94	84	70	68	68	74	64	68	
6	MUTHU	33	1	68	L1 Burst II with paraplegia	Posterior stabilization	1	1	15	10	20	5	75	86	76	70	72	75	78	74	75	
7	DAVID	19	1	50	POTTS paraplegia	Posterior stabilization D8 D9	2	1	15	6	10	5	84	88	80	70	64	64	62	58	60	
8	POOSAM	50	2	60	L5 S1 Spondylolisthesis	Posterior stabilization	1	1	20	8	14	5	72	90*	80	75	68	70	72	79	88	
9	AMUDHA	46	2	55	L4 L5 spondylolisthesis	Posterior Stabilization TLIF	1	1	15	6	12	6	70	85	80	78	76	68	70	68	75	
10	VELU	55	1	68	# L1 with paraplegiaa	Posterior stabilization	2	1	15	6	12	4	76	84	80	74	68	60	58	56	72	
11	CHINNASAMY	28	1	67	D11 II with paraplegia	Posterior stabilization	1	1	15	10	20	4	81	92	86	80	78	70	68	80	82	
12	RIZWANA PRAVEEN	26	2	68	FractureL1 & L2	Posterior stabilization	1	1	20	6	10	6	70	80	76	70	64	62	60	58	60	
13	ELUMALAI	35	1	60	L4 L5 disc disease (HIV, HBV)	Posterior stabilization	2	1	20	6	10	6	80	94	90	84	70	72	68	65	68	
14	PARASHAKTHI	28	2	62	D12 wedge compression Fracture	Posterior stabilization	1	1	15	6	10	6	84	106	98	90	80	70	71	69	71	
15	PUSHPA	50	2	70	L4 L5 disc disease	Posterior stabilization with TLIF	2	1	15	8	14	5	70	79	70	68	60	56	50	64	76	
16	SANJEEVAN	27	1	69	L2 Burst # with left monoparesis	Posterior stabilization	1	1	15	4	12	6	84	100	90	80	72	74	70	68	86	
17	SEKAR	33	1	69	#L1 Vertibra & quadriparesis	Posterior stabilization	1	1	20	4	10	8	80	94	88	70	71	65	62	60	64	
18	VIJAYAN	19	1	60	L1 wedge compressive #	Posterior stabilization	1	1	15	6	10	5	84	101	94	80	78	72	70	68	72	
19	ILAYARAJA	34	1	72	L3-L4 fracture	Posterior stabilization	1	1	20	4	10	6	76	89	80	75	68	64	62	68	71	
20	VIJAYAKUMAR	40	1	70	L5-S1 Spondylolisthesis	Posterior stabilization TLIF	1	1	15	6	10	5	82	92	86	80	78	74	70	68	84	
21	KATHIRVEL	35	1	71	L3 Fracture	Posterior stabilization	1	1	15	6	10	6	74	86	80	74	65	62	60	60	61	
22	RAMESH	42	1	70	D11 II with paraplegia	Posterior stabilization	1	1	15	4	12	7	75	84	80	76	70	65	62	61	58	
23	MUTHULAKSHMI	33	2	68	L5-S1 Spondylolisthesis	Posterior stabilization TLIF	1	1	12	6	10	6	80	90	86	80	68	64	70	72	65	
24	CHITRA	31	2	64	# L1 with Paraparesis	Posterior stabilization	1	1	15	4	10	6	82	95	90	82	65	69	70	72	68	
25	PITCHANDI	33	1	70	# L2 Paraparesis	Posterior stabilization	1	1	15	6	12	7	78	90	86	80	78	72	70	68	70	
26	DHANASEKAR	24	1	66	L4-L5 disc disease	Discectomy	1	1	15	6	10	6	84	98	86	80	78	74	75	80	72	
27	MANI	56	1	69	L4-L5, L5 S1 disc disease	Laminectomy + discectomy	1	1	20	6	12	7	70	78	70	65	60	50	52	59	60	
28	MANJULA	37	2	70	L4-L5 spondylolisthesis	Posterior stabilization TLIF	2	1	15	6	10	6	72	85	80	83	70	71	69	68	71	
29	RAVI	40	1	69	L4-L5 disc disease	Laminectony discectomy	1	1	15	6	10	6	74	80	79	70	72	69	60	68	65	
30	APARNA	19	2	62	L5-S1 Spondylolisthesis	Posterior stabilization TLIF	1	1	20	6	10	6	90	100	90	80	78	80	76	76	79	

S. NO.	NAME	AGE	SEX	WEIGHT	DIAGNOSIS	SURGERY	ASA	GROUP	TIME OF ADMIN AFTER SURGERY	DRUG			HEART RATE								
										ONSET MIN	PEAK MIN	DURATION HRS	HR-BL	HR-0	HR-15 M	HR-30 M	HR-1	HR-2	HR-3	HR-4	HR-5
31	GAJENDRAN	52	1	68	L4-L5 / L1-S1 disc prolapse	Fenestration discectomy	2	2	15	6	16	6	68	90	84	80	78	74	72	70	68
32	VIII	40	2	60	L5-S1 disc prolapse	Discectomy	1	2	12	6	14	6	80	100	80	78	76	70	80	79	82
33	RAJENDRAN	24	1	62	L1# dislocation with paraplegia	Posterior Stabilization	2	2	15	6	12	5	89	86	80	71	73	76	69	72	86
34	AMUDHA	45	2	60	L5-S1 disc prolapse	Laminectomy + discectomy	1	2	14	8	14	5	78	92	86	87	75	73	69	65	84
35	RAJARATHNAM	40	1	70	L4-L5 / L5-S1 disc disease	L4-L5 Laminectomy Post	1	2	15	6	10	4	75	88	75	72	65	70	72	80	94
36	MANOJ	35	1	65	L1 Burst # with paraplegia	Posterior Stabilization	1	2	20	8	16	5	88	90	86	74	72	68	71	75	87
37	CHINNAKULANTHAI	45	2	56	L3-L4 / L4-L5 disc disease	Fenestration discectomy	1	2	15	6	12	5	70	94	80	75	82	76	72	80	82
38	LAKSHMI	63	2	56	L4-L5 Spondylolisthesis	Posterior Stabilization with TLIF	1	2	12	4	10	4	65	80	75	70	72	65	68	70	84
39	PITCHAIPILLAI	25	1	68	L1-L2, L2-L3 degenerative	Posterior Stabilization with TLIF	1	2	15	8	16	4	79	92	85	78	80	78	80	95	70
40	SELVI	35	2	58	L5-S1 disc disease	Fenestration discectomy	1	2	16	6	14	4	80	104	90	86	82	80	83	100	90
41	DHANALAKSHMI	35	2	80	L4-L5 Spondylolisthesis	Posterior Stabilization + TLIF	2	2	15	10	20	5	82	93	86	80	75	72	69	70	90
42	SELVI	37	2	78	L4-L5 disc disease	Posterior Stabilization + TLIF	1	2	16	6	12	6	75	88	84	70	71	65	64	70	69
43	ANDHAL	37	2	55	Potts spine T10,11,12 L345	Posterior Stabilization	2	2	15	6	12	5	79	92	80	76	82	78	80	84	94
44	SUBBULAKSHMI	40	2	68	L4-L5 disc disease	Bilateral Fenestration	1	2	14	8	14	5	82	88	84	73	76	69	80	76	90
45	JAMUNARANI	21	2	55	# D7 8, D10 D11 Vertebra	Posterior Stabilization	1	2	12	6	12	5	90	110	94	93	90	84	80	78	104
46	SAKTHIVEL	26	1	67	L2 Fracture	Posterior Stabilization	1	2	15	8	14	5	80	86	84	73	72	64	71	74	96
47	RAJENDRAKUMAR	53	1	69	L4-L5 disc disease	Posterior Stabilization	2	2	14	6	10	5	64	92	86	80	78	76	80	80	95
48	POONGOTHAI	45	2	68	L3-L4 Osteoporotic compressive #	Posterior Stabilization	2	2	13	6	12	5	76	91	80	75	72	69	80	78	89
49	GANESAN	52	1	67	L3-L4 disc disease with	Posterior Stabilization TLIF	2	2	15	6	16	6	65	94	78	75	72	68	80	75	81
50	PUSHPA	50	2	66	L4 L5 disc disease	Posterior Stabilization TLIF	1	2	15	8	14	4	68	90	75	80	82	78	69	70	88
51	KUPPAN	45	1	70	L4 L5 disc disease	Post Stabilization TLIF	1	2	14	6	14	5	77	88	82	65	62	60	64	70	70
52	NAGARAJ	25	1	65	L3 Fracture	Posterior Stabilization	1	2	15	6	12	5	80	90	84	75	72	76	68	75	70
53	SHANMUGAM	45	1	70	L4-L5 disc disease, canal stenosis	Laminectomy L4 L5	1	2	15	8	14	6	82	93	87	80	75	73	79	69	75
54	MANIKKAVEL	42	1	72	L2-L3 Spondylolisthesis with LCS	Laminectomy + post stabilization	1	2	12	6	14	5	81	89	80	75	80	78	70	83	80
55	ARIVOLI	33	1	68	D10 # with paraplegia	Laminectomy + post stabilization	1	2	15	6	10	5	75	80	73	60	58	62	65	79	65
56	PREMA	50	2	72	L4-L5 spondylolisthesis	Posterior Stabilization TLIF	2	2	15	6	10	5	69	90	82	78	75	72	70	68	84
57	KARTHIK	25	1	60	L1 wedge ampressive #	Posterior Stabilization	1	2	20	8	12	6	82	106	90	86	88	84	85	80	81
58	SURESH	22	1	58	Potts spine D8-D9 with	Posterior Stabilization	2	2	15	6	14	5	76	89	78	75	70	68	70	76	78
59	RAJI	56	1	69	L5-S1 Spondylolisthesis	Post Stabilization TLIF	2	2	15	6	12	5	70	80	76	65	72	64	68	72	89
60	KALAISELVI	42	2	64	L5-S1 Spondylolisthesis	Posterior Stabilization	1	2	20	6	12	3	79	94	90	88	80	81	90	80	78

S. NO.	NAME					SYSTOLIC BLOOD PRESSURE												DIASTOLIC BLOOD PRESSURE										
		HR-6	HR-8	HR-10	HR-12	SBP-BL	SBP-0	SBP-15M	SBP-30M	SBP-1	SBP-2	SBP-3	SBP-4	SBP-5	SBP-6	SBP-8	SBP-10	SBP-12	DBP-BL	DBP-0	DBP-15M	DBP-30M	DBP-1	DBP-2	DBP-3	DBP-4	DBP-5	DBP-6
1	KANNAMMAL	94	78	82	95	130	128	114	116	116	112	108	110	108	132	120	124	118	80	82	76	74	72	74	74	72	72	84
2	PUNITHA	90	82	94	97	140	130	124	122	87	120	118	110	112	110	126	112	136	80	88	78	78	45	72	76	76	76	74
3	RAJINI	94	87	95	81	120	130	122	120	118	114	110	110	108	110	128	122	126	70	86	76	74	76	74	74	74	72	72
4	SELVARAJ	70	68	88	70	130	128	122	110	112	110	112	114	110	112	116	132	120	74	84	82	78	78	76	74	76	72	78
5	ALAMELLAMMA	62	68	92	70	120	130	124	114	110	106	110	110	106	104	112	116	126	70	90	70	70	68	70	70	72	70	72
6	MUTHU	80	80	70	78	130	124	112	114	110	108	110	110	108	128	124	122	120	80	84	80	80	76	76	70	70	70	90
7	DAVID	59	64	68	86	110	122	124	110	112	110	112	110	132	136	130	128	122	70	78	70	72	72	70	72	70	80	88
8	POOSAM	70	68	84	80	130	130	122	120	112	80	110	112	110	110	112	130	116	90	98	74	74	72	50	76	76	74	70
9	AMUDHA	80	80	74	82	134	136	128	122	120	118	110	110	104	116	132	138	130	80	80	78	76	76	78	72	74	72	74
10	VELU	76	69	70	86	150	136	124	110	112	110	110	112	125	108	124	124	110	80	90	76	76	78	74	68	70	80	72
11	CHINNASAMY	79	84	90	90	120	142	130	128	114	110	112	110	122	132	124	132	120	82	80	74	72	70	74	74	74	80	90
12	RIZWANA PRAVEEN	78	75	76	82	110	132	120	110	108	108	81	108	106	108	128	134	120	80	86	80	76	76	70	45	66	68	68
13	ELUMALAI	84	82	84	86	130	130	122	112	118	118	110	110	112	140	112	132	120	80	78	70	70	68	68	70	70	92	72
14	PARASHAKTHI	88	80	84	81	120	122	120	118	110	112	110	100	108	122	128	132	134	70	76	74	74	70	70	68	70	72	80
15	PUSHPA	74	77	77	75	134	130	122	112	110	112	112	110	132	106	126	120	118	84	94	80	80	78	78	76	74	80	88
16	SANJEEVAN	78	82	80	80	110	120	114	110	112	110	108	110	132	120	132	128	110	70	76	74	74	72	74	74	72	90	86
17	SEKAR	77	76	85	88	124	134	130	128	118	118	116	110	112	120	128	132	122	80	96	88	76	76	74	74	74	72	82
18	VIJAYAN	80	87	87	90	148	150	122	118	112	114	112	110	130	121	120	112	130	94	78	78	70	72	72	7	72	90	96
19	ILAYARAJA	80	80	84	82	132	136	120	112	110	112	110	112	110	112	135	134	120	80	82	80	76	76	80	76	74	72	70
20	VIJAYAKUMAR	76	78	82	86	128	120	112	110	108	110	110	100	132	138	112	128	114	78	84	70	70	72	72	72	74	74	80
21	KATHIRVEL	64	80	82	84	140	132	130	128	124	124	124	120	122	138	140	124	120	80	96	84	80	78	78	77	78	78	90
22	RAMESH	60	80	85	80	130	130	128	126	120	118	110	114	110	112	135	126	124	78	86	82	80	80	78	74	74	76	74
23	MUTHULAKSHMI	76	80	82	79	130	130	122	120	120	116	112	114	112	108	118	124	108	80	92	80	74	74	76	74	76	70	68
24	CHITRA	80	84	88	90	128	142	130	128	114	110	112	110	122	132	124	132	120	80	80	74	72	70	74	74	74	80	90
25	PITCHANDI	72	80	84	88	120	120	110	106	104	110	112	114	110	106	134	110	120	80	80	70	68	70	70	70	72	70	72
26	DHANASEKAR	88	90	85	84	114	108	102	100	102	100	102	100	102	100	104	102	110	74	80	78	76	78	74	74	76	76	72
27	MANI	60	64	70	70	140	128	122	110	112	76	79	108	110	124	134	138	110	90	82	80	80	78	40	43	78	76	86
28	MANIULA	68	73	69	80	130	130	110	112	110	108	106	106	106	112	120	125	132	70	88	70	72	70	68	70	70	8	70
29	RAVI	74	72	84	85	130	124	120	120	118	118	110	110	114	124	132	128	124	74	80	78	78	74	72	74	74	76	80
30	APARNA	75	84	90	90	100	120	110	106	102	102	106	108	106	108	120	110	112	60	90	70	72	68	72	64	66	70	70

S. NO.	NAME					SYSTOLIC BLOOD PRESSURE												DIASTOLIC BLOOD PRESSURE											
		HR-6	HR-8	HR-10	HR-12	SBP-BL	SBP-0	SBP-15M	SBP-30M	SBP-1	SBP-2	SBP-3	SBP-4	SBP-5	SBP-6	SBP-8	SBP-10	SBP-12	DBP-BL	DBP-0	DBP-15M	DBP-30M	DBP-1	DBP-2	DBP-3	DBP-4	DBP-5	DBP-6	
31	GAJENDRAN	88	74	78	84	140	129	120	124	124	128	126	120	112	124	130	130	130	84	90	78	80	80	80	78	82	80	78	
32	VIII	98	72	70	92	130	136	110	104	110	112	120	124	120	130	132	128	126	74	88	86	82	76	76	72	72	89	84	
33	RAJENDRAN	82	65	100	80	120	132	128	122	122	120	120	118	110	112	118	122	130	84	74	72	70	68	70	72	70	72	68	
34	AMUDHA	86	70	89	82	130	138	120	118	106	110	112	110	126	132	142	126	120	82	100	88	80	70	72	72	70	70	92	
35	RAJARATHNAM	72	69	94	75	128	130	112	110	112	110	110	112	112	120	118	130	132	74	90	74	76	74	76	74	72	72	90	
36	MANOJ	69	72	88	70	130	124	118	114	116	114	110	108	106	138	110	114	112	70	86	80	78	78	76	76	76	74	92	
37	CHINNAKULANTHAI	89	64	65	92	128	130	122	118	118	116	110	116	110	112	124	130	118	74	82	80	80	78	76	74	76	76	78	
38	LAKSHMI	78	65	79	68	150	140	130	124	110	110	108	108	112	132	112	116	120	90	102	90	80	70	72	70	70	70	70	
39	PITCHAIPILLAI	75	75	93	78	128	130	112	110	112	108	102	106	110	120	124	132	110	80	90	72	72	70	70	72	72	70	92	
40	SELVI	84	99	83	98	134	136	128	122	120	118	110	110	114	116	132	138	130	84	80	78	76	76	78	72	74	72	74	
41	DHANALAKSHMI	69	88	79	91	120	120	118	116	118	110	108	108	112	120	126	112	120	74	88	84	84	87	78	70	72	75	82	
42	SELVI	86	62	90	90	118	118	110	110	110	110	112	110	118	132	124	110	128	70	88	68	66	64	68	70	70	70	80	
43	ANDHAL	76	82	95	82	120	124	110	110	110	110	112	110	120	130	118	124	122	70	78	70	68	64	68	66	68	72	68	
44	SUBBULAKSHMI	75	78	94	78	134	140	124	122	112	110	111	110	110	112	122	108	132	74	92	80	78	76	74	76	74	74	76	
45	JAMUNARANI	95	76	102	84	110	112	110	110	108	108	106	108	110	120	102	124	106	80	84	70	68	70	72	70	68	66	68	
46	SAKTHIVEL	89	70	90	70	120	120	106	108	108	112	110	112	112	108	114	112	122	70	82	76	76	74	74	76	72	70	72	
47	RAJENDRAKUMAR	80	78	94	80	140	130	128	122	116	118	114	112	132	140	112	132	106	94	84	74	76	76	74	76	74	72	86	
48	POONGOTHAI	83	88	74	88	130	146	126	120	118	110	110	114	120	140	132	120	118	80	96	74	74	74	70	70	72	86	90	
49	GANESAN	87	64	72	90	134	132	120	120	116	116	118	112	116	112	122	114	112	80	82	72	74	72	76	76	74	76	74	
50	PUSHPA	75	72	93	74	140	126	120	120	114	114	110	112	110	112	108	112	134	78	88	80	78	78	74	74	74	74	72	
51	KUPPAN	90	90	82	85	130	134	124	114	112	114	110	112	112	132	128	142	112	85	86	74	74	76	74	72	74	72	90	
52	NAGARAJ	88	75	94	76	112	112	110	110	108	110	110	110	116	132	132	124	130	75	82	76	74	76	74	72	70	80	88	
53	SHANMUGAM	94	72	90	92	134	138	120	120	110	108	110	110	110	112	130	108	132	80	92	72	70	72	72	70	72	74	90	
54	MANIKKAVEL	88	88	72	88	131	122	120	114	110	108	110	110	112	128	134	120	124	85	88	86	76	74	70	70	72	72	90	
55	ARIVOLI	72	60	75	69	138	132	130	128	124	124	124	120	122	138	140	124	120	94	96	84	80	78	78	77	78	78	90	
56	PREMA	75	70	89	70	140	128	122	114	110	102	104	104	100	118	122	124	130	84	88	80	80	74	72	74	72	70	68	
57	KARTHIK	94	75	98	78	124	134	114	110	112	110	110	106	104	108	122	130	104	64	80	74	74	72	72	72	60	64	64	
58	SURESH	85	92	79	88	124	138	118	110	110	108	110	110	114	128	110	112	116	85	98	80	76	76	74	76	72	72	70	
59	RAJI	70	60	90	74	144	130	120	120	118	118	112	114	112	110	124	130	124	85	80	78	78	76	76	74	78	76	78	
60	KALAISELVI	99	79	80	90	139	136	130	124	120	114	112	126	131	132	138	132	104	85	90	88	86	86	82	8	78	76	78	

S. NO.	NAME				MEAN ARTERIAL PRESSURE													VISUAL ANALOG											
		DBP-8	DBP-10	DBP-12	MBP-BL	MBP-0	MBP-15M	MBP-30M	MBP-1	MBP-2	MBP-3	MBP-4	MBP-5	MBP-6	MBP-8	MBP-10	MBP-12	VR-0	VR-2	VR-4	VR-6	VR-8	VR-10	VR-12	VR-14	VR-16	VR-18	VR-20	
1	KANNAMMAL	88	78	74	97	97	89	88	87	87	85	85	84	100	99	93	89	6	6	4	2	2	2	2	0	0	0	0	
2	PUNITHA	90	86	76	100	102	93	93	59	88	90	87	88	86	102	95	96	4	4	4	4	2	2	2	0	0	0	0	
3	RAJINI	84	88	74	87	99	95	89	89	87	87	89	85	89	81	100	95	4	4	2	2	2	0	0	0	0	0	0	
4	SELVARAJ	76	84	82	93	101	91	89	90	87	86	86	84	85	99	99	91	4	4	4	2	2	2	2	0	0	0	0	
5	ALAMELLAMMA	80	78	84	87	103	88	85	82	82	83	85	82	83	91	91	98	4	4	4	4	4	2	2	2	2	2	0	
6	MUTHU	96	80	72	97	97	91	91	87	87	83	83	83	103	105	94	88	4	4	4	4	4	2	2	2	2	2	0	
7	DAVID	80	84	88	83	93	88	85	85	83	85	83	97	104	97	99	99	4	4	4	2	2	2	0	0	0	0	0	
8	POOSAM	76	82	78	103	109	90	89	85	60	87	88	86	83	88	98	91	4	4	4	4	2	2	2	0	0	0	0	
9	AMUDHA	73	84	73	98	99	95	91	91	91	85	86	86	88	93	102	92	4	4	4	2	2	2	0	0	0	0	0	
10	VELU	82	78	82	103	105	92	87	89	86	82	84	95	84	96	93	91	4	4	4	2	2	2	0	0	0	0	0	
11	CHINNASAMY	78	72	82	95	101	93	91	85	86	87	86	94	104	93	92	95	4	4	4	4	4	2	2	2	2	2	0	
12	RIZWANA PRAVEEN	74	76	90	90	101	93	87	87	83	57	80	81	81	92	95	100	4	4	4	2	2	0	0	0	0	0	0	
13	ELUMALAI	76	82	90	97	95	87	84	85	85	83	83	85	95	88	99	100	4	4	4	2	2	0	0	0	0	0	0	
14	PARASHAKTHI	76	84	82	87	91	89	89	83	84	82	83	84	94	83	100	99	6	6	4	2	2	0	0	0	0	0	0	
15	PUSHPA	76	74	90	101	106	94	91	89	89	88	86	97	94	93	89	90	4	4	4	4	2	2	2	0	0	0	0	
16	SANJEEVAN	92	78	74	83	91	87	86	85	86	85	85	104	97	105	95	86	4	4	2	2	2	2	0	0	0	0	0	
17	SEKAR	90	76	80	95	109	102	93	90	89	88	86	85	95	103	95	94	4	4	2	2	2	0	0	0	0	0	0	
18	VIJAYAN	92	76	74	112	102	93	86	85	86	84	85	103	104	101	88	93	4	4	4	2	2	0	0	0	0	0	0	
19	ILAYARAJA	90	86	74	97	100	93	88	87	91	87	87	85	84	105	102	89	4	4	2	2	2	0	0	0	0	0	0	
20	VIJAYAKUMAR	90	74	72	95	96	84	86	84	85	85	86	93	99	97	92	86	4	4	4	2	2	0	0	0	0	0	0	
21	KATHIRVEL	82	84	82	100	108	99	96	93	93	93	92	93	106	101	97	95	4	4	4	2	2	0	0	0	0	0	0	
22	RAMESH	90	80	82	95	101	97	95	93	91	86	87	87	87	105	95	96	4	4	2	2	2	2	0	0	0	0	0	
23	MUTHULAKSHMI	80	78	72	97	105	94	89	89	89	87	89	84	81	93	93	84	4	4	4	2	2	0	0	0	0	0	0	
24	CHITRA	78	72	82	96	101	93	91	85	86	87	86	94	104	93	92	95	4	4	2	2	2	0	0	0	0	0	0	
25	PITCHANDI	74	72	76	93	93	83	81	81	83	84	86	83	83	94	85	88	4	4	4	2	2	2	0	0	0	0	0	
26	DHANASEKAR	74	82	68	87	89	86	84	86	83	83	84	85	81	84	89	82	4	4	4	2	2	0	0	0	0	0	0	
27	MANI	98	78	76	107	97	94	90	89	52	55	88	87	99	110	98	87	4	4	4	2	2	2	0	0	0	0	0	
28	MANJULA	88	90	82	90	102	83	85	83	81	82	82	81	84	99	102	99	4	4	4	2	2	0	0	0	0	0	0	
29	RAVI	92	86	84	93	95	92	92	89	87	86	86	89	95	105	100	97	4	4	4	2	2	0	0	0	0	0	0	
30	APARNA	78	74	76	73	100	83	83	79	82	78	80	82	83	92	86	88	4	4	4	2	2	0	0	0	0	0	0	

S. NO.	NAME				MEAN ARTERIAL PRESSURE													VISUAL ANALOG											
		DBP-8	DBP-10	DBP-12	MBP-BL	MBP-0	MBP-15M	MBP-30M	MBP-1	MBP-2	MBP-3	MBP-4	MBP-5	MBP-6	MBP-8	MBP-10	MBP-12	VR-0	VR-2	VR-4	VR-6	VR-8	VR-10	VR-12	VR-14	VR-16	VR-18	VR-20	
31	GAJENDRAN	92	84	82	103	104	92	95	95	96	94	95	91	93	103	99	98	4	4	4	2	2	2	2	2	0	0	0	
32	VIJI	84	88	90	93	104	94	89	87	88	88	89	93	99	100	101	102	6	6	4	2	2	2	2	0	0	0	0	
33	RAJENDRAN	70	80	82	96	93	91	87	86	87	88	86	85	83	86	94	98	4	4	4	2	2	2	0	0	0	0	0	
34	AMUDHA	78	74	82	98	113	99	93	85	85	85	83	87	105	99	91	95	4	4	4	4	2	2	2	0	0	0	0	
35	RAJARATHNAM	80	78	76	92	103	87	87	87	87	86	85	85	100	93	95	95	4	4	4	2	2	0	0	0	0	0	0	
36	MANOJ	88	80	78	90	93	93	90	91	89	87	87	85	107	95	91	89	4	4	4	4	2	2	2	2	0	0	0	
37	CHINNAKULANTHAI	76	88	80	92	93	94	93	91	89	88	89	87	89	92	102	93	4	4	4	2	2	2	0	0	0	0	0	
38	LAKSHMI	82	90	76	110	115	103	95	83	85	83	83	84	91	92	99	91	4	4	2	2	2	0	0	0	0	0	0	
39	PITCHAIPILLAI	78	74	74	96	103	85	85	84	83	82	83	83	101	93	93	86	4	4	4	4	2	2	2	2	0	0	0	
40	SELVI	73	84	73	101	99	95	91	91	91	85	86	86	88	93	102	92	6	4	4	2	2	2	2	0	0	0	0	
41	DHANALAKSHMI	80	72	68	89	99	95	95	94	89	83	84	87	95	95	85	85	4	4	4	4	4	2	2	2	2	2	0	
42	SELVI	82	90	74	86	98	82	81	79	82	84	83	86	97	96	97	92	4	4	4	2	2	2	0	0	0	0	0	
43	ANDHAL	80	90	80	87	93	83	82	79	82	81	82	88	89	97	101	94	4	4	4	2	2	2	0	0	0	0	0	
44	SUBBULAKSHMI	102	86	76	94	108	95	93	88	86	88	86	86	88	109	93	95	4	4	4	4	2	2	2	0	0	0	0	
45	JAMUNARANI	82	86	78	90	93	83	82	82	84	82	81	82	85	89	99	87	8	6	4	2	2	2	0	0	0	0	0	
46	SAKTHIVEL	78	88	80	87	95	86	87	85	87	87	85	84	84	90	96	94	4	4	4	4	2	2	2	0	0	0	0	
47	RAJENDRAKUMAR	90	88	74	109	99	92	91	89	89	89	87	92	104	97	103	85	4	4	4	4	2	2	2	0	0	0	0	
48	POONGOTHAI	72	74	80	97	102	93	86	85	86	84	85	103	104	101	88	93	4	4	4	2	2	2	0	0	0	0	0	
49	GANESAN	80	84	80	98	99	88	89	87	89	90	87	86	87	94	94	91	4	4	4	2	2	2	2	2	0	0	0	
50	PUSHPA	74	86	90	99	101	93	92	90	87	86	87	86	85	85	95	105	4	4	4	4	2	2	2	0	0	0	0	
51	KUPPAN	88	86	72	100	102	91	87	88	87	85	87	85	104	101	105	85	4	4	4	2	2	2	2	0	0	0	0	
52	NAGARAJ	98	74	72	87	92	87	86	87	86	85	84	96	102	109	91	91	4	4	4	2	2	2	0	0	0	0	0	
53	SHANMUGAM	92	94	80	98	107	88	87	85	84	83	85	86	97	105	99	93	4	4	4	4	2	2	2	0	0	0	0	
54	MANIKKAVEL	92	82	76	100	99	97	89	80	83	83	84	85	103	106	95	92	4	4	4	2	2	2	2	0	0	0	0	
55	ARIVOLI	82	84	82	109	108	99	96	93	93	93	92	93	100	101	97	95	4	4	4	2	2	0	0	0	0	0	0	
56	PREMA	82	80	88	103	101	94	91	80	82	84	83	80	85	95	95	102	4	4	4	2	2	0	0	0	0	0	0	
57	KARTHIK	80	84	88	84	98	87	86	85	85	85	75	77	79	94	99	93	6	4	4	4	2	2	0	0	0	0	0	
58	SURESH	80	82	84	98	111	93	87	87	85	87	85	86	89	90	92	95	4	4	4	2	2	2	2	0	0	0	0	
59	RAJI	78	72	80	105	97	92	92	90	90	87	90	88	89	93	91	95	4	4	4	2	2	2	0	0	0	0	0	
60	KALAISELVI	96	92	78	103	105	102	99	97	93	91	102	105	104	110	105	87	4	4	4	2	2	2	0	0	0	0	0	

S. NO.	NAME	PAIN SCALE												RESCUE ANALGESIC REQUIREMENTS												RAMSAY SEDATION SCALE												COMPLICATIONS					
		VR-30	VR1	VR2	VR3	VR4	VR5	VR6	VR7	VR8	VR9	VR10	VR12	1	2	3	4	5	6	7	8	9	10	12	R-0	R-15	R-30	R1	R2	R3	R4	R5	R6	R8	R10	R12	PONV	HYPO	BRADY	RES.DEP	PRU	DELIRIUM	
1	KANNAMMAL	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	2	2	2	2	1	2	2	0	0	0	0	0	0	
2	PUNITHA	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	23	2	2	2	2	2	2	2	1	2	2	0	1	2	1	0	0	
3	RAJINI	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	1	1	2	2	2	3	3	2	2	2	2	2	2	0	0	0	0	0	0	
4	SELVARAJ	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	nil	1	nil	nil	1	nil	2	2	2	2	3	3	3	2	2	2	1	1	0	0	0	0	0	
5	ALAMELLAMMA	0	0	0	0	0	4	2	2	2	2	4	2	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	3	2	3	2	2	2	2	1	0	0	0	0	0	0		
6	MUTHU	0	0	0	0	0	0	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	3	2	3	2	2	2	1	2	2	0	0	0	0	0	0		
7	DAVID	0	0	0	0	0	0	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	2	3	3	2	2	2	2	1	0	0	0	0	0	0		
8	POOSAM	0	0	0	0	0	0	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	3	2	3	2	2	1	1	2	0	1	0	0	0	0	
9	AMUDHA	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	3	2	3	2	1	2	2	0	0	0	0	0	0	
10	VELU	0	0	0	0	0	4	2	2	2	2	4	2	nil	nil	nil	nil	1	nil	nil	nil	nil	1	nil	1	2	2	3	3	3	2	1	2	2	1	1	0	0	0	0	0	0	
11	CHINNASAMY	0	0	0	0	0	4	2	2	2	2	4	2	nil	nil	nil	nil	1	nil	nil	nil	nil	1	nil	2	2	2	3	3	3	2	1	2	2	1	1	0	0	0	0	0	0	
12	RIZWANA PRAVEEN	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	2	3	3	2	1	2	2	0	1	0	0	0	0	
13	ELUMALAI	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	2	2	2	3	2	2	3	3	2	1	2	2	0	0	0	0	0	0	
14	PARASHAKTHI	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	3	3	3	3	3	2	1	2	2	0	0	0	0	0	0	
15	PUSHPA	0	0	0	0	0	6	4	2	2	2	4	2	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	2	2	2	3	3	3	2	2	2	2	1	2	0	0	1	0	0	0	
16	SANJEEVAN	0	0	0	0	0	0	2	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	3	3	2	1	2	2	2	0	0	0	0	0	0	
17	SEKAR	0	0	0	0	0	0	0	0	0	4	2	2	nil	nil	nil	nil	nil	nil	nil	nil	1	nil	nil	1	2	2	3	3	3	2	2	2	1	2	1	1	0	0	0	0	0	
18	VIJAYAN	0	0	0	0	0	0	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	3	3	2	2	1	2	2	0	0	0	0	0	0		
19	ILAYARAJA	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	3	2	2	2	1	2	2	0	0	0	0	0	0	
20	VIJAYAKUMAR	0	0	0	0	0	2	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	nil	1	2	2	3	2	2	3	2	1	2	2	2	0	0	0	0	0	0	
21	KATHIRVEL	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	2	3	3	2	1	2	2	0	0	0	0	0	0	
22	RAMESH	0	0	0	0	0	0	0	0	4	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	3	3	2	2	1	2	2	0	0	0	0	0	0	
23	MUTHULAKSHMI	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	3	3	2	2	1	2	4	0	0	0	0	0	0	
24	CHITRA	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	2	2	2	3	3	3	3	2	1	2	2	2	0	0	0	0	0	0	
25	PITCHANDI	0	0	0	0	0	0	0	0	4	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	3	3	3	2	2	1	2	2	0	0	0	0	0	0	
26	DHANASEKAR	0	0	0	0	0	0	0	4	2	2	4	2	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	3	3	3	2	2	1	2	2	0	0	0	0	0	0	0	
27	MANI	0	0	0	0	0	0	0	0	4	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	2	2	2	2	3	3	3	2	2	1	2	1	0	2	2	0	0	0	
28	MANJULA	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	2	2	2	3	3	3	2	1	2	1	2	0	0	0	0	0	0		
29	RAVI	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	3	3	3	2	2	2	1	2	0	0	0	0	0	0		
30	APARNA	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	3	3	3	2	2	2	2	1	0	0	0	0	0	0		

S. NO.	NAME	PAIN SCALE												RESCUE ANALGESIC REQUIREMENTS												RAMSAY SEDATION SCALE												COMPLICATIONS						
		VR-30	VR1	VR2	VR3	VR4	VR5	VER6	VR7	VR8	VR9	VR10	VR12	1	2	3	4	5	6	7	8	9	10	12	R-0	R-15	R-30	R1	R2	R3	R4	R5	R6	R8	R10	R12	PONV	HYPO	BRADY	RES.DEP	PRU	DELIRIUM		
31	GAJENDRAN	0	0	0	0	0	0	0	4	0	0	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0
32	VIJI	0	0	0	0	0	0	2	4	0	0	2	2	nil	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0
33	RAJENDRAN	0	0	0	0	0	2	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0
34	AMUDHA	0	0	0	0	0	2	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	2	2	2	2	2	2	2	1	2	2	0	0	0	0	0	0	0
35	RAJARATHNAM	0	0	0	0	2	4	2	2	2	2	4	2	nil	nil	nil	nil	1	nil	nil	nil	nil	1	nil	1	2	2	2	2	2	2	1	2	2	1	2	1	0	0	0	0	0	0	
36	MANOJ	0	0	0	0	0	2	4	2	2	2	4	2	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	
37	CHINNAKULANTHAI	0	0	0	0	0	2	4	2	2	2	4	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	1	0	
38	LAKSHMI	0	0	0	0	0	4	2	2	2	2	4	2	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0		
39	PITCHAIPILLAI	0	0	0	0	0	4	2	2	2	2	4	2	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	2	3	2	2	2	2	2	2	2	0	0	0	0	0	0		
40	SELVI	0	0	0	0	0	4	2	2	2	4	2	2	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	3	3	2	2	2	2	2	2	2	0	0	0	0	0	0		
41	DHANALAKSHMI	0	0	0	0	0	0	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	3	2	2	2	2	2	2	3	1	0	0	0	0	0	0		
42	SELVI	0	0	0	0	0	0	2	4	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	2	2	2	3	2	2	2	3	2	2	2	1	0	0	0	0	0	0			
43	ANDHAL	0	0	0	0	0	0	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	3	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0		
44	SUBBULAKSHMI	0	0	0	0	0	0	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	2	3	2	2	2	1	2	0	0	0	0	0	0			
45	JAMUNARANI	0	0	0	0	0	2	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	3	2	2	2	2	1	1	2	0	0	0	0	0	0		
46	SAKTHIVEL	0	0	0	0	0	0	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	2	2	3	2	2	2	1	1	1	0	0	0	0	0	0		
47	RAJENDRAKUMAR	0	0	0	0	0	2	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	3	2	3	3	2	1	2	1	0	0	0	0	0	0		
48	POONGOTHAI	0	0	0	0	0	0	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	2	3	2	2	2	2	1	2	2	0	0	0	0	0	0		
49	GANESAN	0	0	0	0	0	0	0	4	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	2	2	3	2	2	1	2	0	0	0	0	0	0			
50	PUSHPA	0	0	0	0	0	4	2	2	2	2	2	4	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	2	2	3	2	2	2	1	2	2	1	0	0	0	0	1	0		
51	KUPPAN	0	0	0	0	0	0	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	2	2	2	1	2	1	2	0	0	0	0	0	0			
52	NAGARAJ	0	0	0	0	0	2	4	2	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	2	2	3	2	2	1	2	0	0	0	0	0	0			
53	SHANMUGAM	0	0	0	0	0	0	2	4	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	3	2	2	2	3	1	2	2	0	0	0	0	0	0			
54	MANIKKAVEL	0	0	0	0	0	2	4	2	2	2	4	2	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	2	2	2	2	2	2	1	2	1	2	0	0	0	0	0	0			
55	ARIVOLI	0	0	0	0	0	2	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	1	1	2	2	2	2	3	2	2	2	1	2	1	2	0	0	0	0	0	0		
56	PREMA	0	0	0	0	0	2	4	2	2	2	4	2	nil	nil	nil	nil	nil	1	nil	nil	nil	1	nil	1	3	2	3	3	2	2	2	2	2	1	0	0	0	0	0	0			
57	KARTHIK	0	0	0	0	0	0	2	4	2	2	2	2	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	2	2	2	2	2	2	2	1	2	2		0	0	0	0	0	0			
58	SURESH	0	0	0	0	0	2	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	3	2	2	2	2	3	2	1	2	2	1	0	0	0	0	0	0		
59	RAJI	0	0	0	0	0	0	4	2	2	2	2	4	nil	nil	nil	nil	nil	1	nil	nil	nil	nil	1	1	2	2	3	2	2	2	1	2	1	2	0	0	0	0	0	0			
60	KALAISELVI	0	0	0	2	4	2	2	2	4	2	2	2	nil	nil	nil	1	nil	nil	nil	1	nil	nil	1	2	2	2	3	1	2	2	1	2	1	2	0	0	0	0	0	0			